**Universidade de Aveiro** Secção Autónoma de Ciências da Saúde
**Ano 2014/ 2015**

**Catarina Martins Gomes**

# Estágio na Lenitudes Medical Center & Research – Gestão da Qualidade

# Traineeship in Lenitudes Medical Center & Research – Quality Management

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# Traineeship in Lenitudes Medical Center & Research – Quality Management

Relatório apresentado à Universidade de Aveiro para cumprimento dos requisitos necessários à obtenção do grau de Mestre em Biomedicina Farmacêutica, realizado sob a orientação científica do Professor Doutor Francisco Luís Maia Mamede Pimentel, Diretor Clínico da Unidade de Saúde Lenitudes Medical Center & Research e da Professora Doutora Alexandra Isabel Cardador de Queirós, Professora Coordenadora da Escola Superior de Saúde da Universidade de Aveiro.

“*Put your heart and soul into even your smallest acts. This is the secret of success.”*

Swami Sivananda

**o júri**

| | |
|---|---|
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**palavras-chave**

Biomedicina Farmacêutica, Lenitudes Medical Center & Research, Gestão da Qualidade, Acreditação, Certificação, Dispositivos Médicos, Investigação Clínica

**resumo**

O presente documento pretende descrever um estágio curricular realizado na clínica *Lenitudes Medical Center & Research,* localizada em Santa Maria da Feira, que decorreu durante 10 meses, acompanhando o processo de construção, abertura e entrada em funcionamento desta nova estrutura de saúde.

A formação académica proporcionada pelas unidades curriculares do Mestrado em Biomedicina Farmacêutica permitiu o desenvolvimento de conhecimentos e competências nas áreas de Investigação Clínica, Regulamentação e Desenvolvimento de Dispositivos Médicos e Gestão da Qualidade que puderam ser colocados em prática durante esta experiência.

O estágio focou essencialmente tópicos relacionados com a Gestão da Qualidade, com os respetivos processos de desenvolvimento do seu Sistema e da respetiva documentação, visando possíveis estratégias futuras para a Acreditação e Certificação desta unidade de saúde. Durante o estágio, adicionalmente, foram realizadas atividades de carácter multidisciplinar relacionadas com a procura, organização de propostas de orçamento e seleção de dispositivos médicos e, ainda, alguns processos iniciais de investigação clínica.

O estágio curricular revelou-se bastante enriquecedor e único, tendo permitido o desenvolvimento de novas competências e aptidões profissionais, pessoais e sociais.

**keywords**

Pharmaceutical Biomedicine, Lenitudes Medical Center & Research, Quality Management, Accreditation, Certification, Medical Devices, Clinical Research

**abstract**

This document aims to describe a traineeship developed in the healthcare unit Lenitudes Medical Center & Research, located in Santa Maria da Feira, which had a duration of 10 months, following the process of construction, opening and start functioning of this new health facility.

The academic training provided during module courses of the Master Degree in Pharmaceutical Biomedicine allowed the development of knowledge and skills in the areas of Clinical Research, Regulatory and Medical Devices Development and Quality Management which have been put into practice during this experience.

The traineeship focused, essentially, on topics related to quality management, respective documentation and development processes of its system, with the objective to outline future strategies for this clinic's accreditation and certification. During this traineeship, I additionally developed multidisciplinary activities related to search, organization of medical devices' budgets and selection and, also, some initial processes regarding clinical research.

The traineeship has proved very enriching and unique, having enabled the development of new professional, personal and social skills.

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# List of Abbreviations:

| | |
|---|---|
| AC | Administration Council |
| ACSA | Agencia de Calidad Sanitaria de Andalucia |
| ACSS | Administração Central do Sistema de Saúde (Central Administration of Health System) |
| CCPC | Clinical Care Program Certification |
| CEC | Comissão de Ética Competente (Competent Ethics Committee) |
| CEIC | Comissão de Ética para a Investigação Clínica (Ethics Committee for Clinical Research |
| CEISUC | Centro de Estudos e Investigação em Saúde da Universidade de Coimbra (Studies and Research in Health – University of Coimbra) |
| CHKS | Caspe Healthcare Knowledge Systems |
| CNPD | Comissão Nacional de Proteção de Dados (National Comission for Data Protection) |
| CT | Computerized Tomography |
| DGS | Direção-Geral de Saúde (Health Direction) |
| DICOM | Digital Imaging and Communications in Medicine |
| EEIG | European Economic Interest Grouping |
| EFQM | European Foundation for Quality Management |
| EN | Norme Européenne (European Standard) |
| ERS | Entidade Reguladora de Saúde (Health Regulatory Entity) |
| ESMO | European Society for Medical Oncology |
| EUNetPaS | European Network for Patient Safety |
| FMUC | Faculdade de Medicina da Universidade de Coimbra (Medicine College of University of Coimbra) |
| GCP | Good Clinic Practise |
| HAS | Haute Autorité de Santé |
| HL7 | Health Level Seven International |
| IARC | International Agency for Research on Cancer |
| ICH | International Conference on Harmonisation |
| IPO | Instituto Português de Oncologia (Portuguese Oncology Institute) |
| IPQ | Instituto Português da Qualidade (Portuguese Institute of Quality) |
| ISO | International Organisation for Standardization |
| ISQua | International Society for Quality in Health Care |
| JCAHO | Joint Commission on Accreditation of Healthcare Organisations |

| | |
|---|---|
| JCI | Joint Commission International |
| JSCC | Journal of Supportive Care in Cancer |
| KIS | "Keep it Simple" |
| Lenitudes MC&R | *Lenitudes Medical Center & Research* |
| MAPA | Monitorização Ambulatória da Pressão Arterial (*Ambulatory* Blood Pressure *Monitoring)* |
| NICE | National Institute for Health and Care Excellence |
| NP | Norma Portuguesa (Portuguese Standard) |
| OECD | Organisation for Economic Co-operation and Development |
| OECI | Organisation of European Cancer Institutes |
| PDCA | Plan, Do, Check, Act |
| PET | Positron Emission Tomography |
| PI | Principal Investigator |
| QMS | Quality Management System |
| R&D | Research and Development |
| SIES | Serviço de Instalação e Equipamentos (Service of Installations and Equipment Maintenance) |
| SGS | Société Générale de Surveillance S.A |
| SOP | Standard Operating Procedure |
| SPECT | Single Photon Emission Computed Tomography |
| UA | Universidade de Aveiro |
| UKAS | United Kingdom Accreditation Service |
| USF | Unidade de Saúde Familiar |
| WHO | World Health Organisation |

# 1 Introduction

This document describes the activities and skills developed during the traineeship in Lenitudes Medical Center & Research (Lenitudes MC&R), within the scope of the master's degree in Pharmaceutical Medicine. The formal traineeship period started in 15th of September and ended in 17th of April, although the contact between both parts begun earlier, in 2nd of June. Since the clinic is a new healthcare unit built from scratch, I had the opportunity to follow its creation and development from early on the process. For that reason, the majority of the traineeship activities were performed in provisory installations in Hotel Ibis, in Sta. Maria da Feira, watching from close, the progression and evolution of the clinic's construction and equipping.

The main core of this report and the traineeship were tasks related to quality management including the collaboration on the development of Standard Operating Procedures (SOP), creation of record standards, development of the quality management plan which included strategies to create and improve the quality management system and strategies for accreditation and certification. Nevertheless, several trainings on quality management and other activities were performed, such as activities of administrative nature, management, contact with medical devices' suppliers and tasks related to clinical research.

## *1.1 Objectives*

The traineeship objectives were divided into those needed to conclude the master's degree, those related to collaboration on the projects and work within the host company, and finally, the aims related to personal development.

Thereby, the following represent the goals required for master's conclusion:

- To develop the plan for quality management of the host company;
- To start the creation of the quality management system;
- To collaborate on the creation of SOPs;
- To understand the National health Accreditation Programme;
- To understand other Accreditation models such as Joint Commission International (JCI), Caspe Healthcare Knowledge Systems (CHKS) and Organisation of European Cancer Institutes (OECI);
- To know the International Organization for Standardization (ISO) standards applicable to healthcare services' units and certification processes;
- To collaborate on the assurance of company's compliance with regulatory clinical legislation and applicable standards;

- To know the regulatory national legislation related to private healthcare units;
- To know the regulatory national legislation applicable to nuclear medicine and radiotherapy services;
- To know the medical devices' market, specifically the medical devices' suppliers;
- To face the health market and the reality within a healthcare unit.

Regarding the host company, adding to the previous referred, the following objectives were defined:

- To collaborate on documentation organization and record;
- To collaborate on the request, record, organization, review and management of the hospital equipment and medical devices' budgets;
- To collaborate on the equipment selection processes;
- To understand the quantity and types of medical devices that a healthcare unit with the Lenitudes MC&R's characteristics, needs to open and to start operating;
- To know the basic requirements and characteristics of each medical device needed in the clinics' services;
- To understand the material and human resources that are required for this healthcare unit.

Personally, I identified the following personal aims to be achieved at the end of the traineeship:

- To be adapted to professional life and to clinical environment;
- To be prepared to face the labour market;
- To recognize my difficulties and strengths and to improve it;
- To have been able to contribute to the success of the projects were I was involved and to the company's success;
- To put into practice the knowledge and skills developed during academic training;
- To make connections with people on this sector;
- To increase my knowledge, to grow both professionally and personally.

### *1.2 Host Organization Portrait*

As I referred previously, my traineeship was developed in Lenitudes MC&R, which is a subunit of Lenitudes SGPS company.

**Lenitudes SGPS** is the holding enterprise, located in Lisbon, which includes four other companies related to healthcare services. This holding company comprises the departments of

administration and general management of all the other units involved, project management and legal support.

Lenitudes holds the following units (figure 1 and 2):

- **Lenicare** was the first establishment to open and to start operating and it is a radiotherapy unit located in Évora, being a public-private partnership with the Lenitudes and Hospital do Espírito Santo – Évora.
- **Lenitudes Medical Center & Research**, in Sta. Maria da Feira, was my host company that started being constructed right after Lenicare, and its characterization and further details will be referred further on.
- The "***Hospital Cirúrgico de Setúbal***" and "***Hospital Portimão***" are the units which will be developed after Lenitudes in Sta. Maria da Feira has opened and started operating.

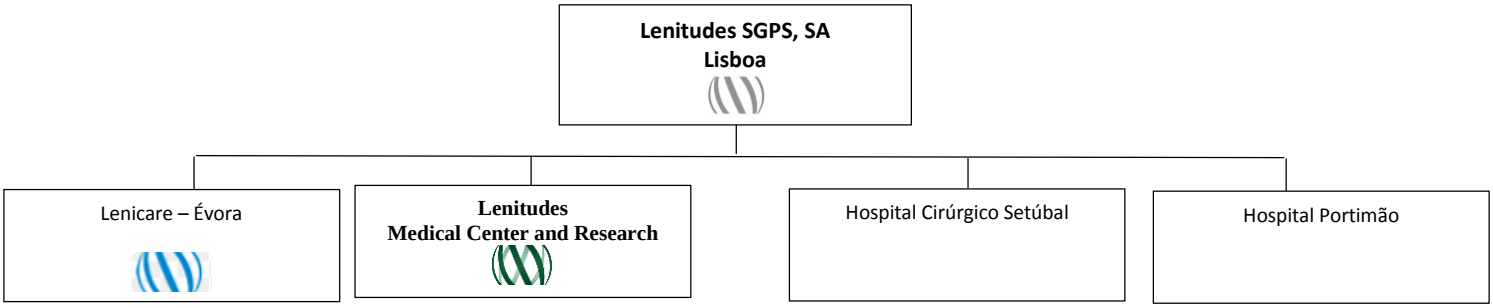



*Figure 1 - Lenitudes SGPS Representation and its clinical units*

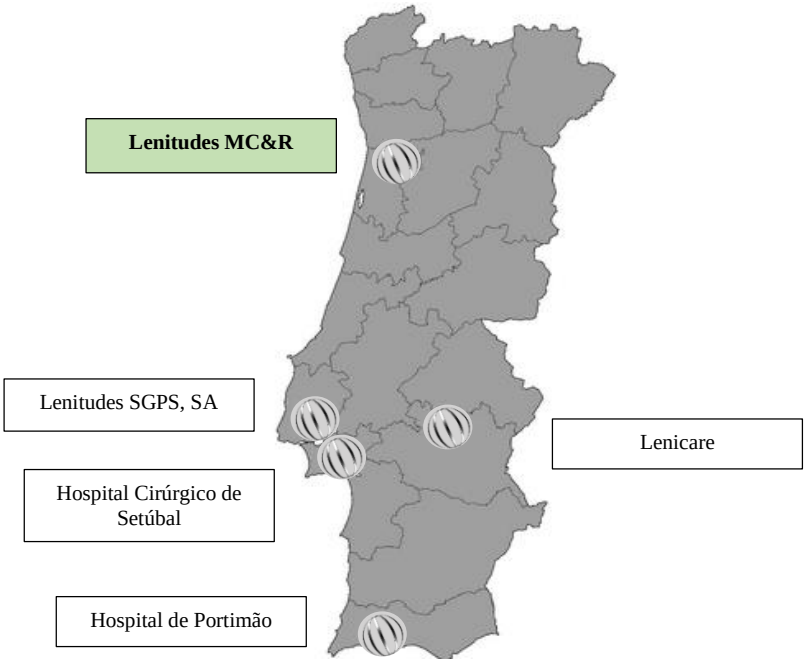



*Figure 2 - Lenitudes units' Location*

### 1.2.1 Lenitudes Medical Center & Research

Lenitudes MC&R was the unit that followed the Lenicare's creation. The construction phase ended in January 2015 (figure 3), enabling the occupation of the clinic's space and the subsequent change of the employees from the temporary facilities - Hotel Ibis - to the clinic.

*Figure 3 – Lenitudes' building image*

The internal structure of the company is represented in figure 4.

As it is shown, Lenitudes MC&R belongs to Lenitudes' group, being administered by some members of this holding company. Prof. Francisco Pimentel, my host training supervisor, is responsible for Lenitudes MC&R's clinical leadership.

As for my traineeship, it occurred in a time where departments and divisions were not defined yet. However it can easily be included in clinical devices/supplies' management and quality management, being presented in figure 4 in yellow colour.

There are some services that are performed by outsourced companies, such as:

- Human resources for Radiotherapy and Nuclear Medicine (except specialist physicians);
- Hygiene and cleaning;
- The sterilization of the surgical and medical instruments and devices;
- The service of waste management;
- The laundry services.

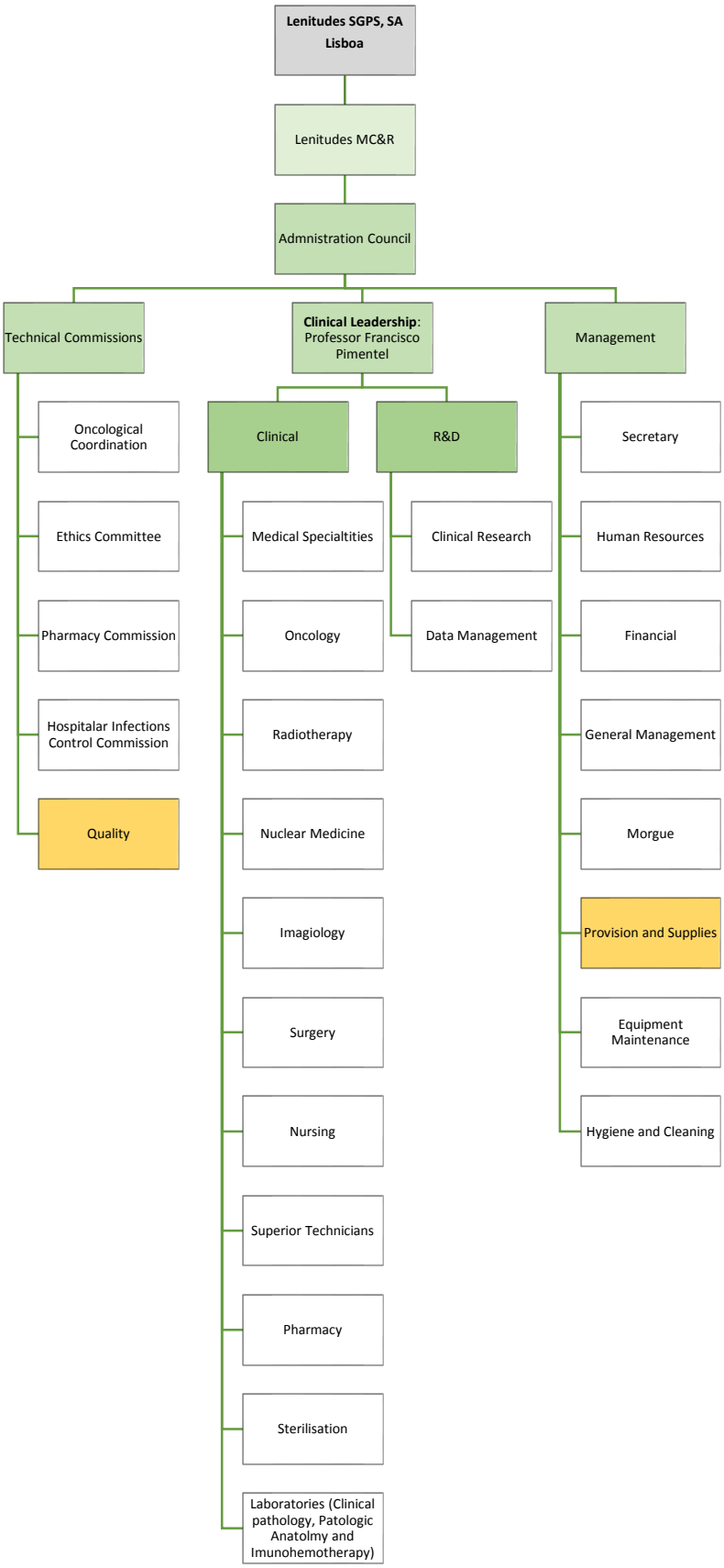



*Figure 4 - Lenitudes MC&R organisation chart's proposal*

This centre located in Sta. Maria da Feira presents a range of clinical services, from diagnose techniques to clinical treatments:

- Nuclear Medicine with two different equipment: one positron emission tomography (*Pet)* and one *g*amma camera single photon emission computed tomography *(SPECT)*;
- Imaging: echography, radiology and mammography, specifically two echo graphs, one echocardiograph, one mammography, one image intensifier and one computerized tomography (CT);
- Radiotherapy: with two accelerators machines;
- Outpatient Surgery: two surgical rooms plus three recovery areas including four bedrooms;
- Chemotherapy (medical oncology): with four individual rooms and one larger room for three or four patients;
- Consultations rooms: one for psychology and nutrition and eight for the following medical specialties:
    - Gynaecology/urology;
    - Otorhinolaryngology;
    - Neurology;
    - Gastroenterology;
    - Anaesthesiology and Pain;
    - Orthopaedic;
    - Psychiatry;
    - Dermatology;
    - Radiotherapy;
    - Nuclear Medicine;
    - Cardiology;
    - Pulmonology;
    - Medical Oncology;
- Oncology Research within two laboratories: one for basic research and another specific for clinical research;
- Palliative care and partnerships with other clinical centres.

Lenitudes MC&R has the ultimate technology, from General Eletrics, corresponding to the cutting-edge technology. In terms of diagnose, the equipment of nuclear medicine includes the

new PET/CT that are only available in two more places worldwide, offering a better image in less time with a much lower dose of radio drugs. The SPECT, the general echo graph, the ultimate model of echocardiograph and the surgery X-Ray arch C are also cutting-edge devices.

In terms of radiotherapy, Lenitudes MC&R will offer a more precise treatment, since the two Elekta accelerators produce a more accurate radiation beam, in a fewer time, causing less collateral damage. Therefore, the healthy cells located near the tumour will hardly be affected. Lenitudes MC&R will also be the training centre of the Iberian Peninsula and the Lusophone world for these devices.

Regarding the surgery, this clinic will use advanced surgical techniques, and even irreversible electroporation procedures. It is going to have the surgical rooms equipped with high technology which will be used by multidisciplinary surgical teams.

Concerning clinical consultations, there will be created geriatric oncology specialised consultations.

On the other hand, the management and clinical assessment of the outcomes generated are also an outstanding method that will allow Lenitudes MC&R to provide a more personalised treatment to each patient, evaluate better the progression or regression of the disease in each patient, in a context of a more personalised medicine, to which the advanced diagnostic devices will also contribute.

The figure 5 represents the Lenitudes' drawing, with the areas and services that it will offer.

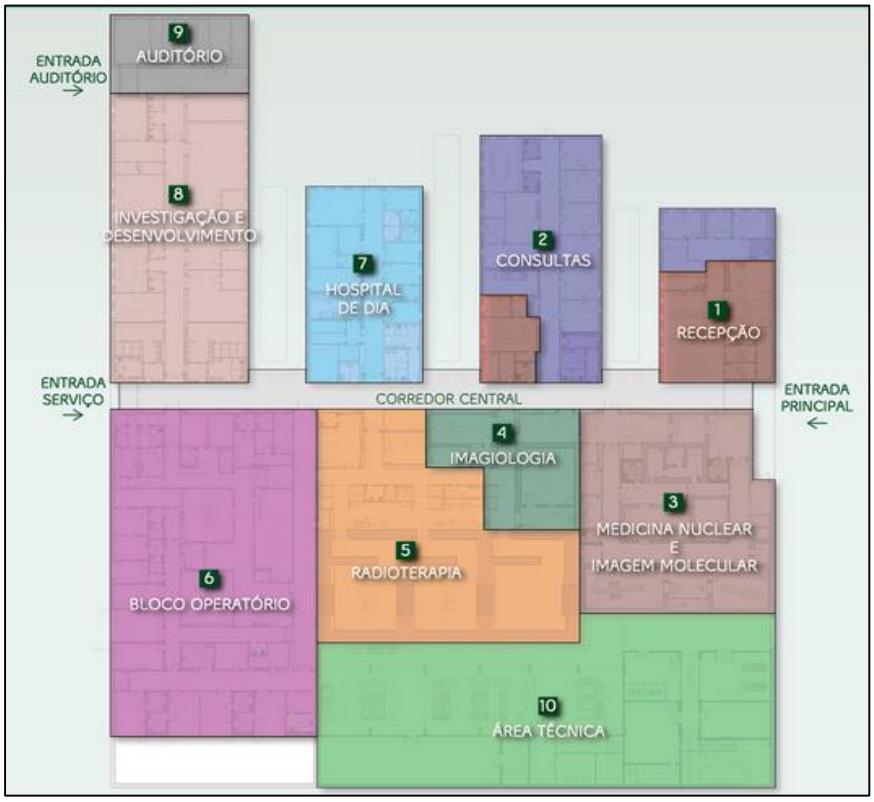



Figure 5 - Lenitudes MC&R's drawing (1 - Reception, 2 - Consultation/Examination rooms, 3 - Nuclear Medicine and Molecular Imaging, 4 - Imagiology, 5 - Radiotherapy, 6 - Surgery, 7 - Day Hospital, 8 - Administration and Research & Development)

Lenitudes MC&R unit pretends to focus and maintain the core in oncological patients and treatment. However it presents more valences: the nuclear medicine devices can be used to diagnose other diseases, the consultations rooms are meant for medical specialties other than oncological, and there is the possibility to perform endoscopic and surgical procedures to other pathologies than cancer. This unit will go even further by offering sleep studies, clinical trials, cardio and neurologic research related to nuclear medicine techniques. The outcomes of each treatment and procedure will be assessed in order to give more representative, valuable and reliable data.

Lenitudes MC&R is also very committed on the quality of the services and its continuous improvement, ensuring the satisfaction of the patient's expectations and needs.

### *1.3 Reports' Structure*

This report is organised in order to present, in this chapter, the host company, followed by a general framework of health, new cases of cancer and the need for health care with better quality. Then, it introduces the subject of Quality Management, identifying and clarifying the accreditation and certification models considered for the company in question. In later chapters, it is presented and explained my experience and activities. In the Discussion chapter, there is an exhibition of my personal opinion, the difficulties I felt and the acquired skills and knowledge.

# 2 General Framework

In Europe, as well as in Portugal, there has been a demographic evolution and an increase on the average of life expectancy. In fact, life expectancy, in Portugal in 2008-2010, presented values of 76.14 years for man and 82.05 years for women, at birth. This demographic evolution characterized by the ageing of population brings particularities in diseases, treatments and in health care [1].

This circumstance allied with population's lifestyle results in the increase on the number of certain diseases, such as cancer. Cancer is, undoubtedly, a current disease that will be even more prevalent in the future. According to International Agency for Research on Cancer (IARC), in European Union, there will be an 13.7% increase on the new cases of cancer, based only on the criterion of the aging of population. Concerning Portugal, it is estimated an increase of 12.6% in new cancer cases (Figure 6 and Figure 7) [2].

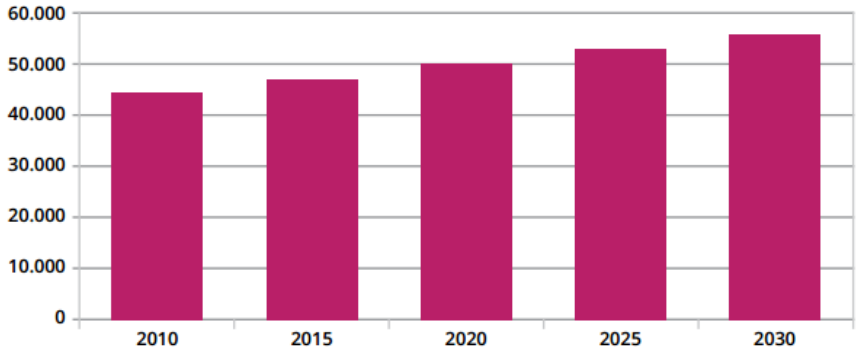



*Figure 6 - Estimated evolution on the incidence of cancer in Portugal (2010 to 2030) [3]*

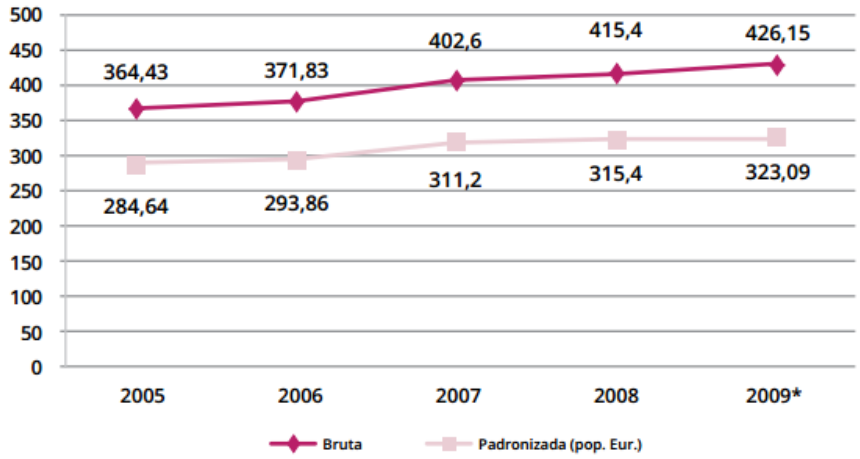



*Figure 7 - Evolution rate on incidence of malignant tumours in Portugal [3]*

In spite of the increase on the number of cases, compared to previous years, the mortality rate has been slightly decreasing, showing positive results in healthcare values. Based on the Health Direction (*Direção-Geral da Saúde* – DGS in Portuguese) report "Cancer Diseases in Numbers –

2014" [3] there has been an increase on radiotherapy services, on the use of cytotoxic and immunomodulating drugs, and on the number of surgeries. Contrarily, there was also a slightly increase in standby time for surgery, in public units [2, 3]. These numbers seem to indicate some difficulties in this type of care. Because of the fact that the public services cannot provide a full coverage of treatments and diagnostic methods to the population, the Portuguese government is starting to understand the importance of collaboration with private services, in order to achieve more effectiveness and innovation, earlier screenings, improvements on oncological surgeries and on the standby times for consultations, treatments and surgeries [2-5].

In fact, the population are also demanding more technical and human resources, enhancing the requirements and needs for each patient [3].

Additionally, and mainly because of the innovation in treatments and surgeries, the number of cancer patients that survive has also been rising, which presents clinical and social particular issues demanding more healthcare services. The population is also becoming more health literate, demanding health services with high standards of quality [2, 3, 6-8].

In terms of quality, as it is well known, the majority of companies, independently of the area/sector where they are inserted, are very concerned about the quality of their products/services. The healthcare units are no exception. As a matter of fact, in Portugal, the public healthcare units and their regulatory authorities, DGS and Health Regulatory Entity (*Entidade Reguladora da Saúde* – ERS in Portuguese), are committed to quality in health, accreditation and certification. The regulatory authorities are promoting this particular issue by providing conferences and meetings. The Calouste Gulbenkian Foundation released a report "A future for Health"[9] defending the promotion, improvement and implementation of quality in health, in order to achieve a sustainable healthcare system with high quality. In a time where financial resources are limited, the quality management takes a crucial role [9].

Since the evaluation and assessment of a service to determine if it has quality or not, is very difficult and subjective, there were created standards of accreditation and certification.

In Portugal, the accreditation of health units has already been started fifteen years ago. During this time, the programs, objectives and methods were changed and decided. Nowadays, the quality in health care plays a greater role [10, 11].

In spite of the commitment of the public health authorities, in public health care, there is still a lack of good quality indicators and objectives and, therefore, on the assessment of quality in health care.

The dissemination of information related to quality in Portuguese healthcare services is also not being effective. In fact, the American organization "Patients Beyond Borders", does not have any information and knowledge about Portugal, concerning quality and patients' numbers [12, 13].

Still, Portugal is creating several incentives to change this paradigm. For instance, the development of the "Sim-Cidadão" to analyse and assess patients' complaints and suggestions related to public healthcare services which are very important to achieve improvements in health. The Central Administration of Health System (ACSS) developed quality objectives associated with incentives or penalties, in the program-contracts with the healthcare centres and hospitals groups.

There are another programs that show the commitment for quality, for example the National Program for Prevention and Control of Infections Associated with Health Care created by DGS; National Incident Reporting System and Adverse Events and Centre for Patient Safety developed by DGS; National Campaign for Hand Hygiene within the "World Health Organisation (WHO) World Alliance for Patient Safety"; or Project Healthcare Associated Infections in European Long Term Care Facilities developed in Project HALT by DGS.

In terms of international companies that promote quality in health, specifically of accreditation there is the international company King's Fund, the Joint Commission International (JCI) and Agencia de Calidad Sanitaria de Andalucia (ACSA). With the focus on patient's management and safety, there is the European Foundation for Quality in Management (EFQM) and European Union Network for Patient Safety (EUNetPaS). Particularly to hospitals there is the World Health Organisation (WHO) integrating Health promotion into Hospitals and Health services, among others. There are also other institutions that promote health quality such as National Institute for Health and Clinical Excellence (NICE) in United Kingdom, Haute Autorité de Santé (HAS) in France and the German Agency for Quality in Medicine in Germany [12].

The Organisation for Economic Co-operation and Development (OECD) is creating the project called "Health Care Quality Indicators", to promote and improve the assessment of quality in health care. This project comprises three types of indicators: the structure indicators, related to the conditions and requirements that the hospital has and needs to operate, and related to the qualification of human resources; the process indicators, associated with the performance of care and if it is intended for the target population; and the outcome indicators, which consist on the results of medical care related to the improvement or impairment of a certain patient's condition. OECD through "Health at a Glance 2013" [14] presents several health indicators with respective data related to health systems from several countries [12, 14].

In Family Health Centres (Unidades de Saúde Familiar (USF) in Portuguese) there are already created indicators of performance to assess the availability, accessibility, efficiency, technical and scientific quality, effectiveness and satisfaction [12] .

In Portugal, there are already twenty six healthcare unites certified by the JCI and CHKS[13].

Despite that information, based on the study "O Estado de Saúde em Portugal, 2009" that assessed the Portuguese opinions, 95% revealed that the national health service needed changes, particularly on the standby times, on the organization and management of resources, on investment and on quality [15].

In reality, there is a trend by patients to search for healthcare services with better quality. Therefore, according to some released media papers, the Portuguese people prefer more the private services, when compared to previous years. Actually, Portuguese are making more contracts with health insurances and using more private healthcare units. According to the Spanish consulting company DBK's report, the companies holding the private healthcare units grew 14% per year from 2000 to 2005 [16, 17].

On the other hand, the health insurance companies are also demanding high quality in the associated healthcare units, in order to diminish the risks related to claims and compensations [18].

Another important aspect to consider is the health tourism, with the trend to grow higher, and to bring profits to national economy. If we check the list of the countries with higher health tourism, we will see Thailand with hospital "Bumrungrad International", which is accredited by JCI [13].

Undoubtedly, in order to reach a greater market, internationalization, and to attract patients from foreign countries within the scope of health tourism, accreditation and certification are essential. To show the quality assurance mark in the services helps to ensure that the clinic is sustainable and improves the confidence in the services. This brand is crucial to promotion and marketing of the services. Quality also contributes to ensure more profits for the company since it is very important to attract more patients. Adding the fact that quality increases collaborators' motivation and satisfaction providing a better service. On the other hand, quality helps to manage more efficiently ensuring profitability to the unit.

Lenitudes SGPS, and Lenitudes MC&R in particular, want to contribute to increase the Portugal presence on the international routes of health tourism, applying to quality improvement and making efforts to turn Medicine more personalised and reliable.

### *2.1 Regulatory Framework*

The new private healthcare units need to comply with several legal requirements. This compliance has extreme importance in order to increase the probability of obtaining licences to start operating. Therefore, below there are presented some of the regulatory documents consulted during the phase of construction and equipping of the clinic:

- Portuguese Decree-law 127/2014 of August 22th, concerning the opening, modification and operation of private health facilities [19];
- Portuguese Decree-law 222/2008 of November 17th, that consists of the standards for safety and protection for the use of ionizing radiation [20];
- Recommendations and technical specifications for hospital units, 2011 by ACSS [21];
- Portuguese Governmental Order Number 33/2014 of February 12th, regarding the opening, modification and operation of private health facilities [22];
- Portuguese Governmental Order Number 34/2014 of February 12th, concerning the opening, modification and operation of private health facilities [23];
- Portuguese Governmental Order Number 35/2014 of February 12th, related with the opening, modification and operation of private health facilities [24].

Quality Management is becoming more obligatory and legislated. For the activities related to quality management and quality in health, the following regulation was consulted:

- Portuguese Governmental Order Number 69/2009 of August 31th, that approves the accreditation model ACSA as the official and national model for accreditation in health care [25];
- Portuguese Decree-law 234/2008 of December 2nd, that gave to DGS the skills to plan and program the policy for the quality in healthcare system [26];
- Portuguese Governmental Order Number 155/2009 of February 15th, the quality in health department was created [27];
- Portuguese Governmental Order Number 14223/2009 of June 24th that approved the National Strategy for Quality in Health care [28].

### *2.2 Quality Management*

Quality, according to EN ISO 9000:2005 standard, can be defined as the

"Degree to which a set of inherent characteristics fulfils requirements"

EN ISO 9000:2005 (page 7) [29]

There are many other definitions, however, quality is, undoubtedly, "doing right at first time", in an efficient and sustainable way, with the involvement of all collaborators, with focus on improvement and on the clients' satisfaction [30-32].

Historically, quality is present at least from Egypt ancient time, having become more important during the industrial revolution. Europe started being more focused on quality since the eighty years with the development of ISO 9000 standards. Portugal also started giving importance to quality management from eighties to nineties with the creation of several entities specific for quality aspects [31, 33, 34].

There are certain names which made a great contribution to quality management such as G. Taguchi with the focus on the reduction on variation, J. M. Juran with trilogy of quality, K. Ishikawa with the importance on Training and Education, P.B. Crosby with the recipe of doing right at first time, A. V. Feigenbaum with the three steps for quality and W.E. Deming, with the cycle PDCA and the fourteen topics needed to achieve quality, among others [31, 35].

Quality management can be define as the activities and actions executed by an entity in order to lead, manage and control their procedures, processes and services/products.

According to ISO standards, there are eight fundamental principles:

1. **Customer Focus:** The basis for the success of the companies is satisfying customer needs and requirements;
2. **Leadership:** This competence is crucial to ensure the engagement of all collaborators and the company's sustainability;
3. **Involvement of People:** The collaborators are the ones who perform the service and their engagement in quality management and improvement of processes is very important;
4. **Process Approach:** The activities and actions must be manage and executed as processes by transforming inputs into outputs, in order to generate measurable and efficient results;
5. **System Approach to management:** The processes must be manage within a system, in which there are inputs which are transformed into outputs;
6. **Continual Improvement:** Search and effort for continuous improvement should be an enduring practice of the organisations;

7. **Factual Approach to Decision-making:** The decisions, especially in health care must be supported by reliable and measurable data;
8. **Mutually beneficial suppliers relationships:** The suppliers are important stakeholders, therefore, in order to enhance quality in both processes and systems, both must work and relate beneficially;

In a generic point of view, and taking as basis the figure 8, the model of quality management encompasses the inputs, which consist of the customer's requirements and needs that are transformed through the process of development of the service/product into outputs which include the costumer's satisfaction. In this cycle there is also the contribution of data measurement, analysis and improvement processes, resources management and leadership and management responsibility [30, 32, 36].

The processes approach model is presented next:

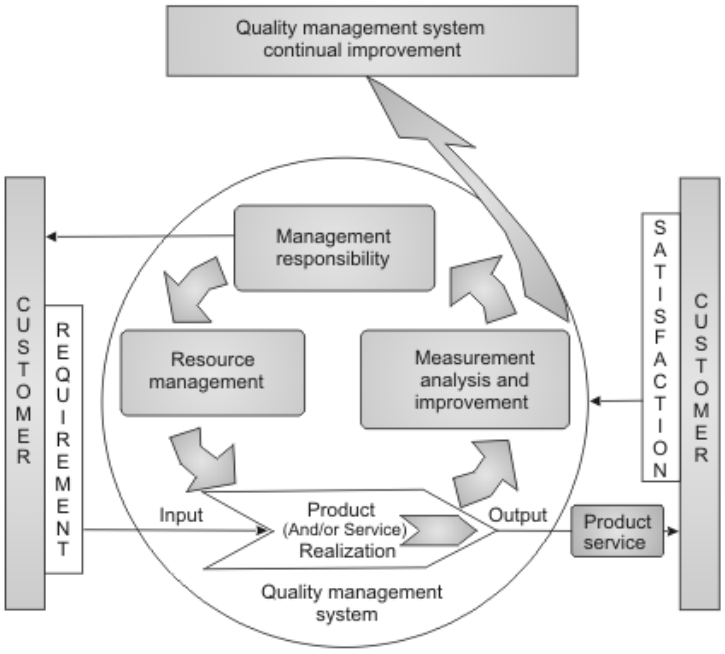



*Figure 8 - Representation of a Processes Approach Model [36]*

In fact, the customers are the key to quality management and continuous improvement:

*"Your most unhappy customers are your greatest source of learning"*

Bill Gates, founder of Microsoft

In order to achieve the continuous improvement, the processes related to development of the service and the quality management should obey to Deming's cycle, also known as the PDCA method, including the following steps (figure 9):

- P "Plan" – To identify the customer's requirements and needs, to determine the policy and objectives for quality within the company, to identify the processes needed to achieve those aims;
- D "Do" – To perform those pre-identified processes and procedures;
- C "Check" – To measure, analyse and manage the outcomes of the processes, in comparison with the customer's requirements, and the policy and objectives of the company;
- A "Act" – Having as basis the analysis previously performed, improve the processes and the outcomes [30].


*Figure 9 - Deming's cycle [37]*

To sum up, quality management requires, firstly, the planning, followed by control and analysis, assurance and continuous improvement [30-32, 34].

The EFQM Excellence model is also an important tool to achieve quality. It can be applied to any organisation, presenting nine criteria, having five "enablers" criteria that refer to "what and how" the company does, and four "results" criteria regarding "what" the company achieves. The first topic of criteria includes subtopics such as leadership, people, strategy, partnerships, resources, processes, products and services. These if well implemented, will result on the following subtopics: people results, costumer, society and business (figure 10).

This model is based on 3 pillars: learning, creativity and innovation [38].

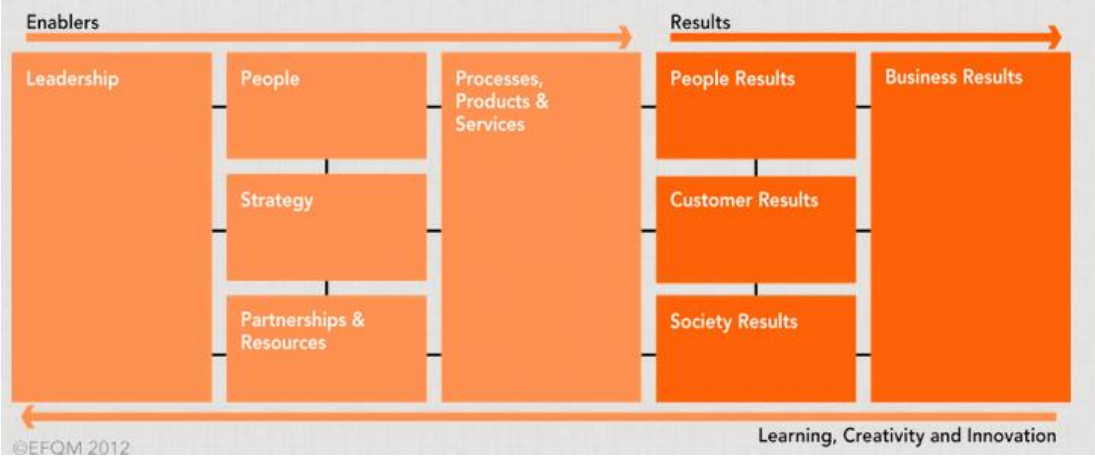



*Figure 10 – EFQM Excellence model [38]*

In healthcare units, it is important to focus not only on quality, but especially on patient's safety and well-being. Quality of care is essential to improve health outcomes [10, 39].

It is also relevant to state that quality should not be focused in a few areas but in all units' organization and structure, infrastructure and mainly in the clinical aspects.

It is extremely important to ensure that medicine is being practised according to high standards and criteria of quality, value, precision and accuracy [10].

### 2.2.1 Accreditation

Accreditation is the process from which an external organisation recognises that Applicant Company is able and has technical competence to perform compliance assessment activities [31, 40].

The healthcare sector presents certain particularities, being the accreditation process defined as the evaluation and recognition that a healthcare organisation meets applicable and pre-identified standards, by an external organisation. Usually, accreditation process applies to the entire company [41, 42].

By saying that, it is clear that accreditation have high importance for the brand and image, enhancing the costumer's confidence and contributing to differentiate from the competitors.

There are some organisations that offer accreditations programmes, as referred before, based on Portuguese National Health Accreditation Programme: CHKS, JCI and ACSA. The OECI was also considered.

In the next sections these organisations will be detailed and clarified [10, 43, 44].

#### 2.2.1.1 Caspe Healthcare Knowledge Systems (CHKS)

This organization belongs to the holding company named “Capita”, which presents a great presence on the processes management of business in United Kingdom, being also present on the European, African and Indian market.

CHKS encompasses two big distinct areas: “Data and Consultancy” by providing support on the identification and measurement of healthcare performance indicators; and “Accreditation” programmes, being present in more than a hundred healthcare units, in Europe.

This company is accredited by International Society for Quality in Healthcare (ISQua) standards and by United Kingdom Accreditation System (UKAS) for ISO Standard 17021:2011, which gives them the ability to certify other organisations by ISO 9001:2008 standard. This way, CHKS can provide accreditation or accreditation plus certification for ISO 9001:2008. Thereby, CHKS ensures a complete programme, certification focused on the quality management system (QMS) and accreditation specific for clinical issues and indicators and patient’s safety.

CHKS presents several accreditation programmes with different requirements, specific for the following areas:

- “Addiction Treatment Centres;
- Care Homes;
- Hospices;
- Full Hospital Accreditation;
- Mental Health Providers;
- Primary Care Teams;
- Oncology Services;
- Risk and Patient Safety;
- Leadership and Corporate Management;
- Maternity and Neonatal Care.”

The programme provided by CHKS, usually, needs fifteen months, from the acceptance of contract, followed by training and questions sessions, audits and delivery of final report. The “award” is granted to the companies that are in compliance with CHKS’s requirements, and can be kept for three years. Then, a new evaluation is needed.

CHKS, already, made accreditation processes in Portugal, in oncology sector, specifically in Portuguese Oncology Institute (IPO) of Porto and IPO-Coimbra. The table 1 presents the structure and the standards listing of the Oncology Programme.

*Table 1 - CHKS's Oncology programme standards listing*

| | |
|---|---|
| **Section 1: Service Delivery** | Standard 1 – Departmental and service management |
| | Standard 2 – Quality Management |
| | Standard 3 – Risk |
| | Standard 4 – Competent Workforce |
| | Standard 5 – Information governance and technology |
| | Standard 6 – Clinical Records Management |
| | Standard 7 – Patient Focus |
| | Standard 8 – Administration and clerical services |
| **Section 2: Clinical Services** | Standard 9 – Radiotherapy |
| | Standard 10 – Radiotherapy Physics |
| | Standard 11 – Chemotherapy |
| | Standard 12 – Outpatient Clinics |
| | Standard 13 – Clinical Trials |
| | Standard 14 – Treatment of children and young people |

For each of the standards presented above there are several requirements that must be fulfilled [10, 43, 45-47].

#### 2.2.1.2 Joint Commission International (JCI)

Joint Commission was created in 1951, consisting of a non-profit organization, which made part of accreditation processes of more than 20.500 healthcare units.

The JCI, founded on 1994, is integrated in "Joint Commission Resources", being part of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). JCI, with accreditation processes, specifically, is spread worldwide among more than ninety countries.

The JCI's main purposes are the patient's safety and quality improvement in health care. The programme includes several international standards that are associated to measurable elements to evaluate the compliance.

This process, in spite of being created by a foreign company, it is fully in compliance with the legal, religion and cultural specificities of each country. JCI reviews its own standards in periods of two years.

The standards can be classified into mandatory or optional, being checked and evaluated during the JCI's audits.

After JCI's assessment, there can be two decisions:

- Accredited: if the applicant company showed minimum results of compliance for all mandatory and optional standards; the company receives the final report and a "award";
- Accreditation denied: When the applicant company didn't show fulfilment of the requirements, or when the company withdraw or even when JCI decides to remove the accreditation decision.

This way, for each requirement, the organization can be classified as "Fully complies", "Complies partially" or "Does not comply".

If an organization is classified with "Does not comply" for certain requirements, there can be developed "follow-up activities" to improve it.

The accredited organisations must renew their award in a period of three years.

JCI also presents several healthcare programmes, however, for the purpose of this report, the only one taken into consideration is the "Joint Commission International Accreditation Standards for Ambulatory Care". This programme can be summarized into:

1. **Accreditation Participation Requirements;**
2. **Patient-Centered Standards:**
    - International Patient Safety Goals
    - Access to Care and Continuity of Care
    - Patient and Family rights
    - Assessment of Patients
    - Care of Patients
    - Anaesthesia and Surgical Care
    - Medication Management and Use
    - Patient and Family Education
3. **Health Care Organization Management Standards:**
    - Quality Improvement and Patient Safety
    - Prevention and Control of Infections
    - Governance, Leadership, and Direction
    - Facility Management and Safety
    - Staff Qualifications and Education
    - Management of Information

JCI also presents a certification programme, named "Clinical Care Program Certification" (CCPC), centred on the assessment of diseases' management. However, the organisations can only apply for this programme when accreditation has been obtained [10, 43, 48-52].

#### 2.2.1.3 Agencia de Calidad Sanitaria de Andalucía (ACSA)

This public entity belongs to Ministry of Equal, Health and Social Politics of Andalucía, Spain. Its central aim is the promotion of the Quality Model of Andaluz.

This programme is the official and national model for Portugal, since 2009, based on Governmental Order Number 69/2009 31st August. [25]

In Portugal, there is a department dedicated to quality in health care named "*Departamento da Qualidade na Saúde"* (Department of Quality in Health), being part of the DGS.

This model provides accreditation, depending on the applicant's will, to all services or only to a few.

This programme is based on 3 pillars of management:

- Management by Processes;
- Clinical Management;
- Management by Competences.

This programme also aims to improve the patient's safety, to ensure competent human resources, a better medicine practice and a better measurement and analysis of the outcomes. This model is associated with an informatics platform, to facilitate the process of communication between auditors and the applicant company and to improve the insertion of data, reducing time and costs.

This model is organized on the topics presented in Table 2:

*Table 2 - ACSA model*

| | |
|---|---|
| **I. The citizen, as the centre of the Health System** | 1. Patients: Satisfaction, Participation and Rights |
| | 2. Accessibility and Continuity of Health care |
| | 3. Clinical Documentation |
| **II. Integration and Continuity of Health care** | 4. Management of healthcare processes |
| | 5. Activities to Health Promotion |
| | 6. Leadership of the organisation |
| **III. Professionals** | 7. Professionals, Education and Evolution |
| **IV. Support Areas** | 8. Structure, Equipment, and Suppliers |
| | 9. Systems, Information and Communication Technology |
| | 10. Quality Systems |
| **V. Outcomes** | 11. Key outcomes in the organisation |

For each of these topics there are several requirements, classified into group I, II or III. In group I, there are standards considered mandatory.

This model, contrarily to the others, present three accreditation levels depending on the compliance of standards of group I, II and III (Table 3).

*Table 3 - ACSA Accreditation levels*

| | Good | Great | Excellent |
|---|---|---|---|
| **Group I** **Nº Standards**: 65 (from which 35 are mandatory) | > 70% (including all the mandatory) | 100% | 100% |
| **Group II** **Nº Standards**: 29 | | >40% | 100% |
| **Group III** **Nº Standards**: 18 | | | >40% |

This program has four phases: the request submission to be accredited, the self-evaluation, the external assessment and the follow-up (lasting for 5 years, after accreditation, with follow-up visits at second and fourth year [10, 43, 53-55].

#### 2.2.1.4 Organisation of European Cancer Institutes (OECI)

The OECI is a non-profit non-governmental organization created in Vienna in 1979, aiming the improvement on oncological care. Its purposes focus on the increase and improvement of communication and collaboration between European cancer institutes.

This organization, already encompasses 68 oncological centres.

The subgroup named "European Economic Interest Grouping" (EEIG) applies its efforts and interests in oncology-related areas. This way, they develop the oncology model that present as principal objectives the cancer centres accreditation, elaboration of clinical guidelines, education and training, creation of new technologies and development of pathobiology studies.

Part of EEIG's mission consists on the increase of "Comprehensive Cancer Centres" which can be defined as cancer centres that implemented efficiently the oncology model, proving that they are competent, capable and have the required resources and equipment to increase and improve the oncological care.

In Portugal, IPO-Coimbra, IPO-Porto and IPO-Lisboa are already associated members of this organization.

The oncology centres that show interest in becoming members of this organization have two options with two different financial amounts (Table 4):

*Table 4 - OECI members' fees*

| | **"Full Member"** | **"Associated Member"** |
|---|---|---|
| **Admission fee** | 5.000€ | 5.000€ |
| **Annual fee** | 5.000€ | 2.000€ |

The accreditation programmed was developed on 2008 and are accomplished by the assessment of two surveys: qualitative and quantitative, supported by an informatics tool.

This programme requires a primary phase of centre's designation on the following:

- "Cancer Units" – Clinical institutions or hospitals that have at least radiotherapy and chemotherapy services or oncological surgery;
- "Clinical Cancer Centre" – Clinical institution with radiotherapy, chemotherapy, oncological surgery and some clinical research projects;
- "Cancer Research Centre" – research unit which develops essentially clinical or fundamental oncological projects;

- "Comprehensive Cancer Centre"

The accreditation processes, usually, lengths 9-12 months, being only advisable its beginning after the unit achieves a minimum level of quality that can be assessed on the self-evaluation phase.

This way, this model presents the following steps:

1. The centre applies for OECI, sending the required documentation;
2. Payment of Phase 1 Fee;
3. Explanatory visit and Designation process;
4. Self- Assessment by oncological centre;
5. Go/No Go decision;
6. Payment of Phase 2 Fee;
7. OECI analysis available documentation and proceeds a local audit with several auditors (peer-review visit). Checks if the designation was appropriate;
8. OECI assesses the audit results and the submitted documentation; OECI divulgates results and comments;
9. The oncological centre must develop an Improvement Plan;
10. If pre-defined compliance with standards, emission of the accreditation certificate and formal designation by OECI;
11. Follow-up process;
12. At the end of 4 years, after accreditation achievement, the process needs to renewal.

The accreditation model presents the following standards (Table 5):

*Table 5 - OECI's standards*

| Chapter | Standards |
|---|---|
| **Chapter 1:** General Standards, Strategic Plan and General Management | 26 standards |
| | 121 sub standards |
| **Chapter 2:** Screening, primary prevention and Health Education | 5 standards |
| | 19 sub standards |
| **Chapter 3:** Care | 10 standards |
| | 30 sub standards |
| **Chapter 4:** Research, Innovation and Development | 14 standards |
| | 45 sub standards |
| **Chapter 5:** Education and teaching | 4 standards |
| | 45 sub standards |
| **Chapter 6:** Patient Related | 6 standards |
| | 30 sub standards |

In total there are 65 standards and 264 sub standards. On the qualitative survey, these standards can be assessed into: “yes”, “mostly”, “partially”, “no”, or “not applicable”. In the quantitative survey there are also fields to fill related to chemotherapy, radiotherapy, surgery, research, general management, among others [56, 57].

### 2.2.2 Certification

Certification is the voluntary process for which an external company verifies the fulfilment of certain requirements and produces an evaluation report that if positive gives a written assurance that a process, a system or service provided by the applicant company is in compliance with the reference requirements and the applicable regulatory legislation [10, 31, 33, 34].

In the healthcare sector, certification usually applies to individuals, programmes or services, but could also apply to entire healthcare organisations [41, 42].

Certification of the healthcare unit is a subsequent process of accreditation, therefore, here, there will only be considered the certification of the QMS, which can be achieved before general accreditation.

The search and effort to achieve certification of the QMS brings several benefits to the applicant company. First, and considering the organizational and structural point of view, it contributes

to the organization and structuring of the procedures, processes, documentation and operating mode of all company departments, enhancing its efficiency. On the other hand, it aids the company to comply with regulatory legislation. Besides, it enhances the relations with all stakeholders, improving the costumer's confidence. In addition, the companies reduce the costs of non-quality and non-conformities, achieving company's profitability [30-34].

The organization ISO (International Organisation for Standardisation) is a non-governmental entity which creates and develops international standards with the aim of increasing quality levels in the companies, through processes standardization [58].

The ISO 9000:2005 standard contains information about "Fundamentals and Vocabulary", supporting the implementation of quality management systems.

The NP EN ISO 9001:2008 (Portuguese and European Standard) clarifies the requirements and basic principles that a quality management system should obey, focusing on the following:

- Documentation: organization, management and control;
- Responsibility of the management/leadership;
- Resources Management;
- Development of the Product/Service;
- Measurement, Analysis and Improvement [30, 32, 59].

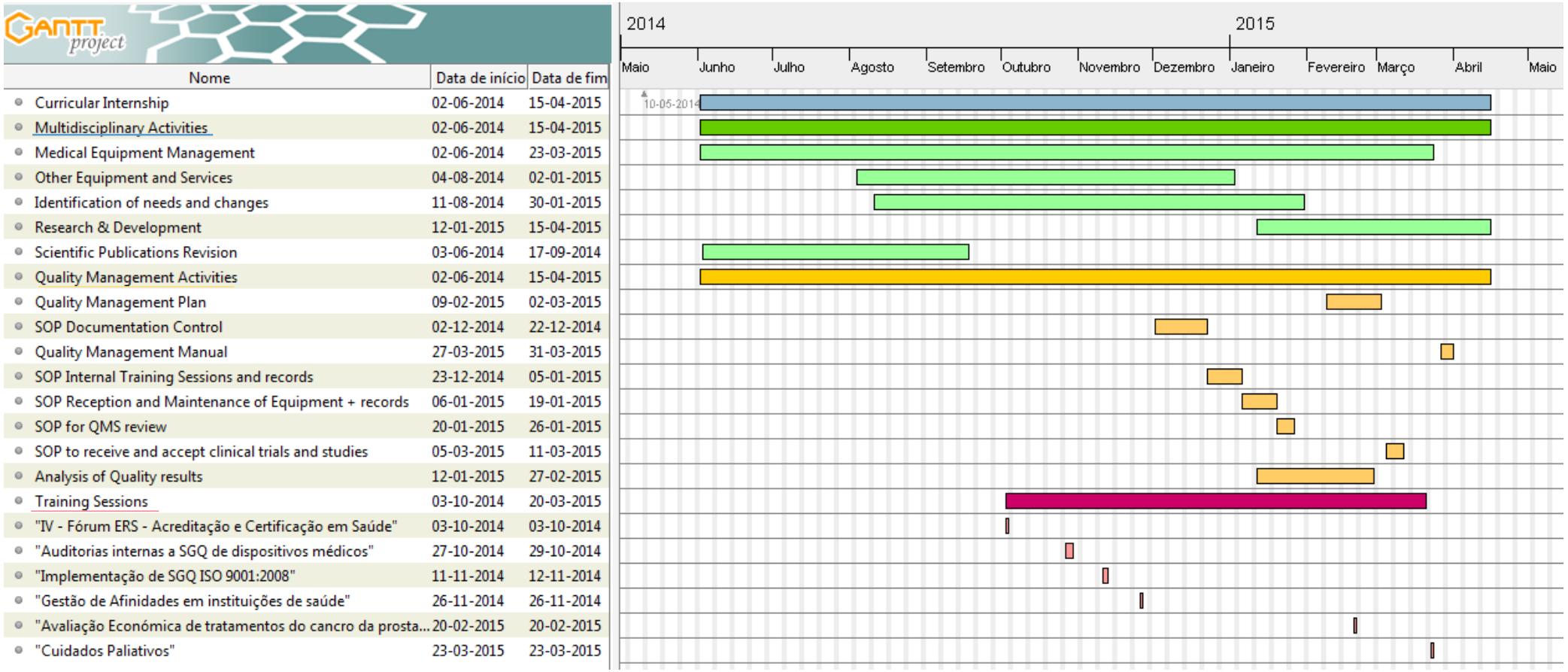
The process of certification of QMS, by ISO standards includes the phase of documentation analysis and supporting/preparation visits, followed by the audit visits and verification of the requirements fulfilment, ending with the final report which encompasses the final decision: to be certified or not. The certified organization is submitted to follow-up audits every year. At the end of three years, the organization is submitted to renewal visits [60].

# 3 Activities developed during Traineeship

The traineeship started at 2nd of June 2014 during the construction phase of Lenitudes MC&R. I had the opportunity to follow the Lenitudes MC&R development. In fact, this was a great opportunity for me to learn the requirements and equipment needed for several clinical rooms: consultation, chemotherapy, preparation of cytostatic agents, radiotherapy and nuclear medicines, surgery and even the equipment's washing, disinfection and sterilization flows, among others. I learnt what "outpatient clinic" means and its services and characteristics. I followed the whole process from the clinic construction until its opening and start functioning.

The traineeship core was quality management activities, including the elaboration of the Quality Management Plan, initial Quality Management Manual, SOPs and standard records. Additionally, there were performed multidisciplinary activities that encompassed the tasks related to the contact with suppliers, budget proposal requests and several meetings that were important to define equipment and other aspects important to clinic's functioning. The time-chart of activities developed during traineeship is presented in Figure 11.

In the next sections are presented the activities related to quality management activities and to multidisciplinary activities.




| Nome | Data de início | Data de fim |
|---|---|---|
| Curricular Internship | 02-06-2014 | 15-04-2015 |
| Multidisciplinary Activities | 02-06-2014 | 15-04-2015 |
| Medical Equipment Management | 02-06-2014 | 23-03-2015 |
| Other Equipment and Services | 04-08-2014 | 02-01-2015 |
| Identification of needs and changes | 11-08-2014 | 30-01-2015 |
| Research & Development | 12-01-2015 | 15-04-2015 |
| Scientific Publications Revision | 03-06-2014 | 17-09-2014 |
| Quality Management Activities | 02-06-2014 | 15-04-2015 |
| Quality Management Plan | 09-02-2015 | 02-03-2015 |
| SOP Documentation Control | 02-12-2014 | 22-12-2014 |
| Quality Management Manual | 27-03-2015 | 31-03-2015 |
| SOP Internal Training Sessions and records | 23-12-2014 | 05-01-2015 |
| SOP Reception and Maintenance of Equipment + records | 06-01-2015 | 19-01-2015 |
| SOP for QMS review | 20-01-2015 | 26-01-2015 |
| SOP to receive and accept clinical trials and studies | 05-03-2015 | 11-03-2015 |
| Analysis of Quality results | 12-01-2015 | 27-02-2015 |
| Training Sessions | 03-10-2014 | 20-03-2015 |
| "IV - Fórum ERS - Acreditação e Certificação em Saúde" | 03-10-2014 | 03-10-2014 |
| "Auditorias internas a SGQ de dispositivos médicos" | 27-10-2014 | 29-10-2014 |
| "Implementação de SGQ ISO 9001:2008" | 11-11-2014 | 12-11-2014 |
| "Gestão de Afinidades em instituições de saúde" | 26-11-2014 | 26-11-2014 |
| "Avaliação Económica de tratamentos do cancro da prosta... | 20-02-2015 | 20-02-2015 |
| "Cuidados Paliativos" | 23-03-2015 | 23-03-2015 |

*Figure 11 – Timechart of Activities developed*

### 3.1 Quality Management Activities

In order to be better prepared to perform quality management tasks, I attended to some training courses, which will be referred further on the chapter 4 “Training Sessions”. Reading and understanding ISO standards were essential such as research and knowledge of the four accreditation models mentioned in previous chapters.

The Quality Management Activities included the development of the following documents:

1. Quality Management Plan for Lenitudes health units;
2. Standard Operating Procedure for documentation control;
3. Quality Management Manual;
4. Standard Operating Procedure for internal Training Sessions;
5. Standard Records related to Internal Training Sessions:
    - Standard Record for Quality evaluation of internal Training Sessions;
    - Standard Record to Register Attendance;
    - Standard Record to Register summary and other observations;
    - Standard Record to promote the Annual Training Sessions Plan;
    - Standard Record to assess efficacy of internal Training Sessions;
    - Standard Record to fill the trainer academic information;
    - Standard Record to enrol participants;
    - Standard Record for survey of training needs;
6. Standard Operating Procedure for reception and maintenance of medical equipment;
7. Standard Records related with maintenance of medical equipment:
    - Standard Record for Technical Assistance Report;
    - Standard Record to register the calibration and verification of medical equipment;
8. Standard Operating Procedure for QMS review;
9. Standard Operating Procedure to receive and accept clinical trials and studies;

Every document developed was according to “keep it simple (KIS)” philosophy to ensure that it will be easily understandable by all collaborators involved.

### 3.1.1. Quality Management Plan for Lenitudes' health units

Initially, I was asked to create an Accreditation Plan for Lenitudes' units. However, I took into consideration the phase in which Lenitudes' units were. Lenitudes MC&R is still on the development phase, not being operating at the date of creation of the plan and without a quality management system. Even Lenicare, that is already operating, does not have any QMS created and implemented. In order to proceed with accreditation, the health unit must be operating, organised and have a QMS implemented, with clinical and quality data, and its analysis of several months. This way, in that initial phase, I thought it was not feasible and useful to create an Accreditation Plan. Instead, I proposed and developed a "Quality Management Plan" to initiate the strategy towards quality. This plan includes a description of the importance of quality to Lenitudes' health units, a general framework with a basic explanation of what is quality, and the accreditation and certification processes. In this plan, it is presented the four accreditation companies with a brief description of each and their advantages and disadvantages for this company. The certification processes presented in this document were based on the certification of QMS by ISO 9001:2008.

The plan also encompasses the strategy for quality and the planning of tasks to achieve it in Lenitudes. This strategy was developed by me and reviewed by Prof. Francisco Pimentel, and refers the approach that Lenitudes should have towards quality.

Considering the accreditation processes, regarding Lenitudes MC&R' characteristics, as an ambulatory oncological healthcare unit, the CHKS programme considered more suitable was oncological programme, presented before on chapter 2.2.1.1.

CHKS was contacted in order to present a cost estimative of the programme for Lenitudes MC&R. It consists of approximately 39.800€ for accreditation and certification and 37.600€ for accreditation only, including the expenses related to travelling, accommodation and food.

The JCI's programme considered more suitable was ambulatory care. The price estimated for ambulatory care units given by JCI was approximately 16.299, 70€, without the costs associated to travelling, accommodation and food. It is estimated, that this cost will be higher at the end of accreditation with the inclusion of all expenses and the value calculation to all services. The certification programme costs on average 5.609, 25€.

The ACSA is the national accreditation model that shows total agreement with the Portuguese legislation. According to an expert contacted, this model used to present costs for public hospital accreditation of approximately 5.000€, including all the expenses related to audits. Nowadays, it can present higher costs and the costs for private units could be very different, therefore it was not possible to assess a precise value.

The OECI model is a specific oncological programme. This model is very specific for cancer dedicated centres, having a large group of criteria that are very specific and detailed. Lenitudes MC&R would be considered "Clinical Cancer Centre" or "Cancer Unit" depending on several factors (such as number of beds, specialists, scientific publications and the budget for care and research) which, according to Table 6, could have a cost from 25.000 to 35.000€ if non-member (Table 6).

*Table 6 - OECI's Accreditation costs*

| | Cancer Units | Clinical Cancer Centres | Comprehensive Cancer Centres |
|---|---|---|---|
| **Members** | 20.000€ | 30.000€ | 30.000€ |
| **Non-Members** | 25.000€ | 35.000€ | 35.000€ |

In terms of certification, the ISO standards which were considered important to Lenitudes, based on the phase of development of the healthcare units and knowing that they don't have, yet, any quality management system, are: NP EN ISO 9000:2005 and NP EN ISO 9001:2008.
The IPQ (*Instituto Português da Qualidade*) was contacted in order to obtain information about the cost of the NP EN ISO 9001:2008, which turned up to be 40,00€.
The company SGS (*Société Générale de Surveillance*) presented a budget for quality management system certification through ISO 9001:2008 standards, of 3.000, 00€ for phase 1 and 2 audits excluding the costs related to accommodation, travel, food and attendance audits.

#### 3.1.1.1 Advantages and Disadvantages of Accreditation Models

The comprehension of accreditation concepts started right on the traineeship's beginning, although the activities developed towards quality started only in December 2014, and predominantly in January and February 2015. I also participated in a meeting with CHKS members Moyra Amess (Director of Accreditation unit) and Ed Watchorn (Business Manager), where they presented their accreditation model.

Concerning CHKS, their online site is a little confused and it is hard and difficult to find information related with accreditation and certification programmes, in comparison to JCI and ACSA. When they were contacted via email, they proved very available, sending the requested information straightaway. They even appointed a meeting and visit to Lenitudes MC&R that occurred at 9th April 2015. Because of the fact that CHKS presents a programme that includes both accreditation and certification allowing the achievement of these processes through high standards of quality in health care and on quality management, they present a big advantage when compared to JCI, ACSA and OECI. Adding the fact that within accreditation programme, there is one plan specific for units with Lenitudes MC&R's characteristics – oncology. The price is similar to OECI's. One disadvantage is the fact that CHKS is much known in Europe but not worldwide. This can impact on the number of foreign clients and in "Health Tourism". Another disadvantage, by the analysis made to the standards available, is that CHKS program should include more requirements for healthcare performance indicators and requirements for healthcare procedures outcomes, specifically in chemotherapy and outpatient services [43, 45-47] .

Regarding JCI, this company also showed very available and send the information required when contacted. Their site is also very friendly, allowing access to a few standards and definitions, making the understanding process a lot easier.
The big advantage of JCI is its big reputation in healthcare sector, presenting a very complete programme, being considered important for Lenitudes, specifically to achieve "Health Tourism". However, this programme is not appropriate for healthcare units that are in development phase. Adding the fact that this model, in spite of being more economic than CHKS, it is still expensive and needs higher amounts of financial resources. This company also does not present specific models for oncological units [43, 50-52].

In regard to ACSA, the first advantage is related to the fact that this model is the accreditation official model for Portugal, showing that it is in complete accordance with the Portuguese legislation. Besides, the model was developed by Spain, for a population that is very similar in terms of epidemiology to Portuguese population [43].This model is also a lot simpler than JCI's, presenting less requirements, and three accreditation levels, being more attractive to units with Lenitudes' characteristics and phase of development. However, ACSA model is not known worldwide, which presents a disadvantage in the "Health Tourism" and internationalization aspects. On the other hand, according to an expert contacted, it has not been any healthcare private unit accredited by this model [10, 43, 44, 54, 55].

Concerning OECI, the model might be a good option for Lenitudes MC&R, since it was developed completely focused on cancer care. The standards seem to cover all aspects related to oncology care, including research that fails to be present on the majority of other models. The costs of this programme are very similar to CHKS's. It can be added that OECI gives accreditation for a period of 4 years, contrarily to the three years period of CHKS and JCI. OECI is not well known globally, not being appropriate for "health tourism" promotion and marketing. On the other hand, this model is only feasible if Lenitudes prefers to acquire this service from different entities, one for Lenitudes MC&R and *Lenicare* and another accreditation company for *Hospital de Setúbal* and *Portimão*, since OECI only grants accreditation to oncological institutions. If Lenitudes decides to acquire this service to only one company, OECI will not be an option [56, 57].

Comparing the accreditation programmes, CHKS also presented an oncology programme, however I could only had free access to a few standards. Therefore I cannot give a precise disclosure on if it is very completed and totally appropriate to Lenitudes.
JCI presented the most economic proposal, but it only presented to "ambulatory care" and by adding the expenses related to audits and services that Lenitudes has, it can increase near the 35.000€. Still, JCI does not have an "oncology programme", in replacement, it has an "ambulatory programme" that may not cover all aspects of oncological treatment.
OECI seems to be of interest for Lenitudes MC&R to become an associate member, independently of accreditation process, to increase their presence among European members.

With reference to QMS certification through ISO standards, this procedure helps the company to organise, develop and consolidate the QMS. It is also important to improve the unit's image.

However, this type of certification is specific only for quality management system and not for clinical indicators and standards. This way, the certification of QMS can be important to structure a healthcare unit, in initial phases. Then it is important to evolve to accreditation of clinical activities [30, 32, 34, 36].

#### 3.1.1.2 Strategy defined

Considering the phase of Lenitudes' health units, it was proposed, first, to create the QMS, as also as the development of measurement and assessment methods of outcomes regarding quality, financial and clinical management. This QMS must be in accordance with ISO standard 9001:2008 and another applicable ISO standards. It must be taken into consideration that a new version of these standards will come during the 2015 year.

The OECI model, since it is available in its online site, it is advisable to be used at least as basis to develop methods to measure and assess clinical outcomes.

After a minimum period of six months of QMS implementation, and after a detailed analysis of suitability, Lenitudes may ask for certification by ISO 9001:2008. A certification plan must be developed before any formal submission.

Then, in a more advanced phase, and depending on the Lenitudes progress towards quality, it must be submitted the accreditation request. In this phase, an accreditation plan must be developed with a new analysis of costs and advantages and disadvantages of each accreditation company. The accreditation company must be selected according to Lenitudes defined strategy: if only one accreditation company to all units (JCI showed more positive and presented strong advantages), or different accreditation companies specific for each unit (OECI for Sta. Maria da Feira and Évora, and JCI for Setúbal and Portimão).

It was also suggested that Lenitudes MC&R should become associate member of OECI, to increase its presence towards oncological care.

This quality management plan also includes a more detailed planning of tasks by showing the order, task description, duration period and correlation between them to create and implement an appropriate and efficient QMS and to achieve high levels of quality in Lenitudes services [30, 33, 34, 43, 45-52, 54-57, 61]. (See annex 1)

### 3.1.2 SOP for documentation control

The SOP for documentation control is essential to develop all documents related to quality management. Therefore, it must be the first document to be created, as referred in Quality Management Plan. Its development was based on ISO 9001:2008, specifically topic 4.2 "Documentation requirements". It aims to ensure that current documents and late versions are correctly identified, that all documents have a person responsible for their creation, revision and approval. The external documents must be identified as such. The obsolete documents must be properly identified, in order to prevent their misuse. The records of documentation are also defined on this SOP. In this document, it is defined the standard structure that all documents must comply with. One example of a structure defined in this document, specific for the following types Policy, Plan, Procedure, Protocol, Agreement, Work Instruction and Safe Instructions, is presented next:

1. Scope;
2. Objectives;
3. Field of application/ Recipients;
4. References;
5. Definitions;
6. Responsibilities;
7. Description;
8. Revision Frequency;
9. List of Revisions;
10. Annexes.

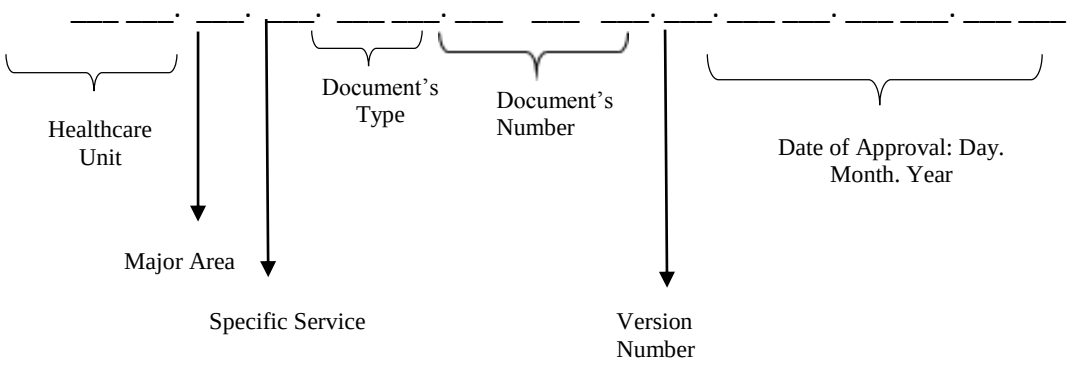
The responsibilities related to documentation development and revision belong to Administration Council and its secretary, service/department coordinator or collaborator within a service, depending on the document's type. The conformity assessment is of quality manager's concern while approval of all documents can be of Administration council or clinical director's responsibility.

Concerning organization and codification of documents, they must be named according to:

- Healthcare unit where they are inserted (*Lenicare or Lenitudes MC&R);*
- Major areas such as Management, Clinical or Support Services;
- The concerned Service within major areas such as Financial, Quality, Oncology, Radiotherapy, or Pharmacy, among others;

- Documents' type – the documents can be classified, according to their content, importance, mandatory character and recipients into 5 levels that include the following: level 1 (Policy, Regulation, Standard, Information) level 2 (Manual) level 3 (Agreement, Plan, Procedure, Protocol) level 4 (Work instructions, Safety instructions Safety Data Sheet, Information leaflet, External Document) and level 5 (Records);
- Date of Approval.

This results in a sequence of 16 numbers separated by dots, as shown in the next scheme:




This way a possible code would be:

Example: 11.2.6.07.001.01.22.12.14

This is a document from Lenitudes MC&R, from clinical area, subgroup of nursing, plan, number 001, 1st version approved in 22th December 2014. (See annex 2)

Regarding the structure, the header and footer of the document are also essential, being clarified in this SOP.

The dissemination and distribution of documents should be controlled and standardised and is also present in this procedure.

The documents in "experimental phase" must also be identified as such.

The process of storage and control of records must also be defined and standardise for all units, being presented and explained in this procedure.

Connected to this procedure are the examples of formatting for safety data sheets, for records, standards and information and the standard for list of QMS documents, external documents and applicable legislation.

This document must be reviewed at least once a year.

This SOP was developed with the collaboration of Clinical Director and Chief Nurse [30, 32, 62, 63]. (See annex 2)

### 3.1.3 Quality Management Manual

I developed an initial version of the Quality Management Manual. This document is essential for unit's organisation and structure. It aims to guide the care services in order to ensure a more sustainable management, increase collaborator's motivation and satisfaction and increase customer's confidence. It represents the quality management system that was created and implemented in an organisation.

It was developed in accordance with ISO 9001:2008 and ISO 9000:2005. It includes a brief description of Lenitudes' structure and organigram. There are some information that weren't available and in these sections of the manual a sentence saying "To be defined by Administration Council later on" is presented.

This document presents information about the main responsibilities of CA, Technical Commissions, Clinical Director, Department/Medical Specialties' coordinator, Collaborators in general and the person responsible for quality. Then, the Manual explains in a general view the Quality Management System, with information about documentation control, management responsibilities, care, research and development, purchases, equipment's verification and calibration, measurement, analysis and improvement, data management and continuous improvement. This document must be reviewed at least once a year, but considering the Lenitudes phase of development, it should be updated every time a new information is identified and approved.

The process that represents quality management system is schemed next (Figure 12): [30, 32, 64, 65]

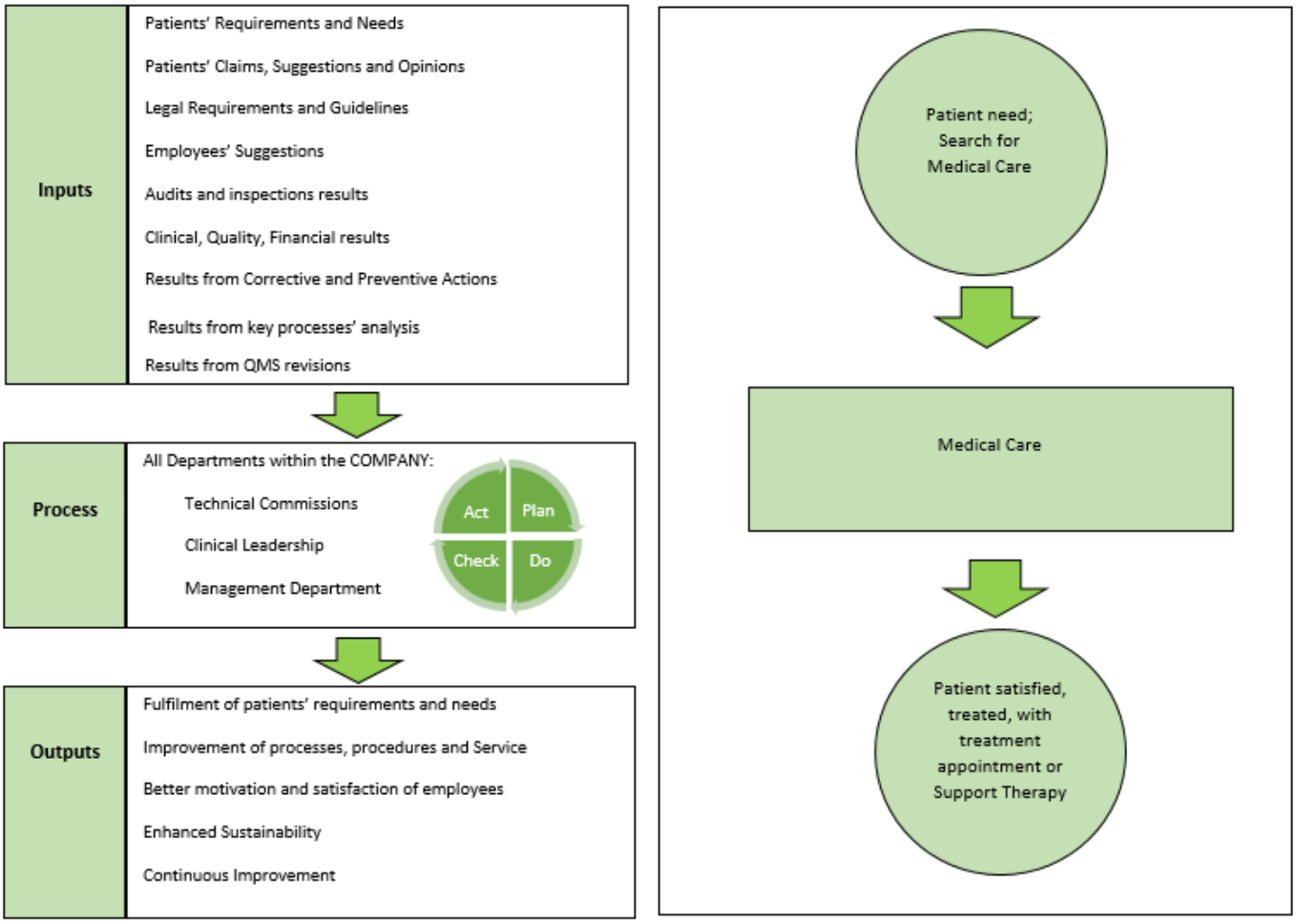



Figure 12 - Scheme representing the process of quality management

### 3.1.4 SOP for internal Training Sessions

This procedure was considered also very important, on the beginning of QMS development, since the clinic was going to admit new employees who need to have training sessions, at least to learn how to use new medical equipment. This procedure unifies the rules concerning to Internal Training Sessions' documentation. Internal Training Sessions are sessions requested internally by the clinical unit, which could have collaboration of external entities. External sessions are not covered by this document. This document is in compliance with SOP of documentation control and ISO 9001:2008, having as responsibilities, mainly the human resources and the trainers. This procedure has several standard records, in order to keep documentation organized, tracked, and updated. It encompasses the process of needs' identification of training sessions, provided by all collaborators, the development of the Annual Training Sessions Plan, the disclosure of Training Sessions, the application process, applications'

records, the documentation required to be fulfilled after each session, the evaluation of efficacy and quality of the session,

All collaborators must be responsible to keep their curriculum vitae updated and they should share this information with human resources.

This document should be reviewed at least once a year, if there is no indication on the contrary.

In order to meet the requirements present in Internal Training Sessions procedure, the following standard records were created and must be used always for issues related to Training sessions: Standard Record for Quality evaluation of internal Training Session; Standard Record to Register Attendance of internal Training Sessions; Standard Record to Register summary and other observations of internal Training Sessions; Standard Record to promote the Annual Training Sessions Plan; Standard Record to assess efficacy of internal Training Sessions; Standard Record to fill the trainer academic information; Standard Record to enrol participants on internal Training sessions; Standard Record for survey of training needs [30].

### 3.1.5 SOP for reception and maintenance of medical equipment

This procedure is also in accordance with standard of documentation control. It was written in compliance with ISO 9001:2008. It bases on two types of maintenance: preventive and curative. This is also an important document, taking into consideration that the clinic was in a phase of reception and testing of material. The responsibilities belong mainly to Service of Installations and Equipment Maintenance (SIES) and management of equipment department. Borrowed equipment should be identified as such. This document also presents a review periodicity of a year [30, 66, 67].

In order to proceed in accordance with reception and maintenance standard procedure I developed two standard records, for technical assistance report and for equipment's calibration and verification, in order to register the actions performed, name and code of equipment and the responsible collaborator, among others [30, 66, 67]. (See annex 3)

### 3.1.6 SOP for QMS review

This procedure is extremely relevant to ensure that QMS is updated and in accordance to predefined objectives and to costumer's expectations. It is also important to achieve continuous

improvement. The responsibilities belong to Administration Council (AC) Clinical Director, Data Manager, Quality Manager and Financial Department.

In this procedure it is defined the inputs to improve QMS such as information suggestions provided by the collaborators, the audits and inspections' outcomes, costumer's opinions and complaints, clinical outcomes, quality indicators, financial indicators, preventive and curative actions' outcomes and oldest versions analysis. The outputs consist of improvement of documents, processes, and quality of overall service.

The QMS should be reviewed continuously, but a more detailed and deep analysis should be perform at least once a year, preferably at the 3 last months of the year[30, 68].

### 3.1.7 SOP to receive and accept clinical trials and studies

This document, contrarily to the others, were not developed because it was important for the initial construction of QMS. Instead, this procedure was created, because I have interest in research issues and with my background knowledge on this concept, I was able to develop it easily. This way, the document will be ready when needed.

This procedure aims to standardise the tasks related to clinical trials and studies in Lenitudes' units. It is in full compliance with Portuguese Law nº 21/2014, 16th April, with Directive EC/2001/20 and ICH Guideline for Good Clinical Practice (GCP). In Definitions section of the document, it is given a clarification of certain concepts such as "Clinical Research", "Clinical Trial", and "Clinical Study with or without intervention". The responsibilities, according to GCP, belong to Medicines and Medical Devices Portuguese Authority, named *Infarmed*, the Competent Ethics Committee (CEC), that can be Ethics Committee for Clinical Research (*Comissão de Ética para a Investigação Clínica* - CEIC in Portuguese) or other appointed or a local Ethics Committee, depending on the type or research, trial, study with intervention or non-interventional study, Data Protection Commission (CNPD), Sponsor and Clinical Research Team. Then, it is proposed several steps with a predefined order that may not be exactly what is stated in the procedure, because this depends and varies according to the sponsor and the type of study. The following steps were defined:

1. Contact between Sponsor and Health Unit;
2. Shipping of first documentation by Sponsor: including Confidential Disclosure Agreement and Feasibility Survey;
3. Qualification Visit: Assessment of centre's characteristics and conditions;

4. Shipping of more documentation by Sponsor: Study Protocol and Investigator's Brochure;
5. Shipping of remaining documentation by Clinical Coordinator: Declaration of Centre conditions; Recruitment method and Declaration of Compensation;
6. Sponsor sends the Financial Agreement and CEC, Infarmed and CNPD's declaration;
7. If applicable, local Ethic committee's opinion;
8. Signature and Date on Financial Agreement and on the Protocol by Administration Council (AC) and Principal Investigator (PI);
9. Shipping of all documentation required to regulatory authorities;
10. Trial's beginning: if Infarmed's authorization, CEC favourable opinion, Financial Agreement and Study Protocol signed and dated and CNPD's authorization.

This document also includes a flowchart with the main steps of this process [30, 32, 69-71]. (See annex 4)

### 3.1.8 Analysis of some Results related with Quality Assessment

In addition, during three events that occurred in Lenitudes, a Research Meeting, a Visit of UA and a training session of software use for physicians, there were delivered surveys to evaluate quality of the sessions where the participants filled with their opinions and suggestions. These results were, then, analysed.

The survey assessed during the first event, the Research Meeting that occurred on 10$^{th}$ January, had a field to fill with personal information such as name, work location, job and contacts. This was important to have access to everyone's contact numbers to create a data base with this information plus the interest of each in research. The second field was about interests of the participant in research projects and in specific areas. The third part of the questionnaire assessed the interest in participating in future research meetings and a table with some evaluation components such as space, schedule, content and organization, which could be assessed in a scale of 1 (bad) to 5 (great). The last field was intended for suggestions or aspects to improve. This resulted, as referred before, in a data base of names, contacts and interests on research that will be of extremely importance to develop future research projects. The results concerning quality of the meeting were very positive with an average of 4.79 in a scale from 1 to 5. There were only two questionnaires not completed filled, with the part of quality

evaluation missing to fill. All suggestions were saved and will be taken into consideration for next meetings.

Concerning the second meeting that occurred in 4th February, it consisted of a visit of some students of the master degree in Technologies of Medical Image of UA, to learn a few concepts regarding Nuclear Medicine and Radiotherapy equipment. There were delivered presence records, and Session Summary record. The Quality Assessment survey was divided into four moments, corresponding to the four phases of the visit. The Evaluation components were:

- The subject of the session was of interest;
- The local was appropriate;
- The audio-visual equipment was adequate;
- The schedule was appropriate and complied;
- The contents met expectations;
- The knowledge learned is useful for academic and professional career;
- The trainer complied with objectives and summary predefined;
- The trainer explained the contents in clear and concise way;
- The trainer showed available for answering questions.

There was also space to fill with comments/suggestions to improve.

Then, the results were analysed. They showed an average of 4.58 in a scale of 1 to 5. The comments were very positive, and even used to publish this event on UA's newsletter. (See annex 5 and 6)

The record use to fill with summary information was improved, since the space to put trainer's name, signature, company and job tittle was missing.

The third event that occurred in 6th of April, was assessed similarly to the second referred before, presenting a final score of 4.87 in a scale of 1 to 5.

All of this documentation is properly stored.

### 3.2 Multidisciplinary Activities

As referred before, I followed the whole process of construction and opening of the Lenitudes MC&R. When I started, in 2nd June 2014, there was only the basic support structure, andeverything related to medical equipment, hospital information software, laundry, waste management and even security services needed to be chosen and selected. These activities were developed during the entire time of traineeship although it focused more on the early months.

Therefore, in the following sections, I will describe the activities performed, in more detail.

### 3.2.1 Medical Equipment

#### 3.2.1.1 Identification/ Definition of Medical Devices

Primarily and during the phase of clinics equipment the feedback and opinion from the physicians that were going to work in the clinic was essential. The majority of medical devices were initially appointed by the Clinical Director and Chief Nurse, based on their experience. The medical equipment specific for a certain specialty such as anaesthesia, surgery, cardiology, otorhinolaryngology, genecology, urology, pulmonology, nuclear medicine, among others, were specifically asked to the future medical coordinator of each medical specialty. I have participated on several meetings with physicians to identify needs, to provide catalogues and medical devices' proposals, and to select the preferred equipment.

The supplier companies were also important sources to identify needs. Based on this information lists of medical devices were developed and continuously updated.

#### 3.2.1.2 Contacting with medical devices suppliers and requesting budgets

In the first day of internship, it was explained the core of my tasks related to accreditation processes advisable to Lenitudes MC&R, and all the other activities that were important to ensure that Lenitudes MC&R would have the best equipment at best prices. This way, I was requested to search on internet for medical devices suppliers, to make contact with then and ask prices for medical equipment. Some companies had already been contacted by Professor Francisco Pimentel, in this case I did the follow-up.

I contacted several medical devices suppliers, listed in Table 7.

*Table 7 - List of suppliers and budgets requested*

| Name of the company | Medical Equipment budget requested |
|---|---|
| **Actual Way** | • Chemotherapy chair<br>• Stretchers<br>• Chairs for blood collection<br>• More clinical furniture |
| **Aegen** | • Chemotherapy chairs |
| **Bacelar** | • Clinical furniture (cabinets and benches)<br>• Complete Medical Devices' Catalogue, including , some specific for operating room such as Anaesthesia system, Pendent for surgery and anaesthesia, surgical table, Mayo, Instrumental and auxiliary table, and others needed for the remaining clinical areas such as hospital cars (transport, anaesthesia, emergency, and nursing procedures), serum holders, vital sign monitors, beds and stretchers and balances |
| **Iberdata** | |
| **Bbraun** | • Syringes and infusion pumps<br>• Some endoscopic equipment |
| **Cardiosolutions** | • Equipment for stress and lung function tests |
| **Cenatolim** | • Complete Medical Devices' Catalogue, including , some specific for operating room such as surgical table, Mayo, Instrumental and auxiliary table, and others needed for the remaining clinical areas such as hospital cars (transport, anaesthesia, emergency, and nursing procedures), beds, stretchers, balances and refrigerators |
| **Salutec** | |
| **Endoxim** | • Equipment specific for otolaryngology specialty |
| **Eurocasmédica** | • Surgical devices<br>• Endoscopic Equipment |
| **Olympus** | |
| **Teprel** | |
| **Fresenius Kabi** | • Syringes and infusion pumps |
| **PMH** | |
| **Frilabo** | • Laminar flow hood<br>• Refrigerators<br>• Blood agitators<br>• Microscopes |
| **Geranswers** | • Vital sign monitors |

| | |
|---|---|
| **Iberconcept** | • Technical Panel for Operating Room |
| **IMO** | • Class I Medical devices such as beds and stretchers<br>• Hospital chairs and clinical bedside table |
| **Industrial Laborum** | • Clinical furniture (cabinets and benches) |
| **Johnson & Johnson** | • Gynaecological equipment<br>• Medical Devices washer and sterilization equipment |
| **LaboSistema** | • Laminar flow hood |
| **Maquet** | • Surgical Tables |
| **Medicinália Cormédica** | • Complete Medical Devices' Catalog, including , some specific for operating room such as Anesthesia system, Pendent for surgery and anesthesia, surgical table, Mayo, Instrumental and auxiliary table, and others needed for the remaining clinical areas such as hospital cars (transport, anesthesia, emergency, and nursing procedures), serum holders, vital sign monitors, beds and stretchers. |
| **Mundinter** | |
| **MoonSurge** | • Surgical Medical Devices |
| **Pulmocor** | • Equipment for stress and lung function tests |
| **Remper** | • Refrigerators |
| **Sechrist** | • Hyperbaric Oxygen Therapy Equipment |
| **Simmedica** | • Endoscopic Equipment |
| **SpaceMedical** | • MAPA (*Ambulatory Monitoring* of *Arterial Pressure)* |
| **Wanrooemed** | • Chemotherapy chairs |

In order to keep medical devices suppliers' contacts organised and available, I created an Excel document with a list of all suppliers, name of the representing person and the respective contact.

The contact with suppliers were made according to the following aspects/steps:

1. A brief introduction about Lenitudes MC&R, the Lenitudes' group and the hospital units that are under construction;
2. The importance of the medical devices supplier's collaboration and their partnership;

3. The fact that Lenitudes seeks for a global supplier to have the majority of equipment at lower prices;
4. The Companies, then, would make a brief presentation of themselves referring their presence on Portuguese and on foreign territory; they would appoint the needs and requirements to supply the clinic, delivering a budget proposal to every equipment considered important to clinics functioning.

At late phases, some companies were contacted specifically to present budget for certain equipment, being the process referred above a little different.

Two foreign companies (Aegen and Wanrooemed) were contacted to supply the chemotherapy chairs, so I had the opportunity to practice my English and learn that it is not advisable to buy medical equipment to a company that does not have a representative in Portugal, because of maintenance and assistance matters. Besides, a Portuguese company that sells this device was then found.

I have visited IMO installations, Class I medical devices producer, and I had the opportunity to watch closely the production of a hospital bed.

I have participated in fifty one face meetings with medical devices suppliers. One of those meetings was entirely in English language.

From all the suppliers contacted (total of thirty one different companies), only thirteen sold medical equipment to Lenitudes.

#### 3.2.1.3 Budget Proposals Management

The budget proposals were delivered via two ways: face-to-face on paper, and digital via e-mail or pen-drive.

All the proposals received on paper were digitalised or it was asked to the supplier company to send it in digital form through email.

In my email account, I created a major folder called “Suppliers” with several folders inside corresponding to each supplier company. A folder identified as “proposed orders for Administration” was created to retain the emails send by me or by Prof. Francisco Pimentel with the suggestions of the equipment to buy, to AC’s approval and following acquisition.

In my computer, I created a major folder, as well, with the name “Suppliers” with several folders inside with the catalogues and proposals sent by the companies.

#### 3.2.1.4 Prices and characteristics Comparison

In order to compare the prices from different suppliers, I developed the following Excel documents:

- Excel document with list of medical equipment by room; with information about the article number, brand, price for unit and price in total for each supplier. The higher prices were represented in red while the lower were on green color. I developed fifty one Excel documents with these characteristics specific for each clinical room. It was important to have a global vision of the equipment required for each room and to negotiate with suppliers (see annex 7);
- Excel document with list prices by type of medical equipment; for example one document for vital signs monitor device; with information on all suppliers for that device, information on article number, brand, price for unit and price in total for each supplier. I developed thirty four Excel documents with these characteristics for some medical equipment. This was important to facilitate the prices perception of a particular device (See annex 8).

Since in these documents, the prices were easily visualized, they were crucial to negotiate with suppliers to obtain lower prices and to choose the supplier company.

Regarding characteristics of medical equipment, I developed some word and pdf documents (in total thirty three) specific for each type of medical equipment with devices' characteristics, images and prices, of each supplier. These documents were then sent to physicians that were going to work in the clinic in order to give their opinion and feedback.

#### 3.2.1.5 Model and Brand selection

The decision and selection of devices brand was based on the following topics:

- Importance and need of medical device;
- Medical Device's characteristics and functioning;
- Feedback from Physician;
- Price;
- If the equipment can be included in a global order with a global supplier;
- Assurance time;

- Maintenance and technical assistance time to respond and associated cost;
- If the equipment is aimed to produce an image outcome, the equipment must had the capability of generating the outcome on DICOM format;
- Every device that generates graphic or parameters should have the capability of being connected to Hospital Software through HL7 protocol.

The process of brand and model selection needed favourable opinion by specialist physician and approval by Clinical Director. This process would then be sent, with a clinical proposal/suggestion of acquisition, to AC to approve or disapprove this decision and to proceed with the following order steps.

### 3.2.2 Other Equipment and Services important for Lenitudes MC&R

#### 3.2.2.1 Hospital Equipment

Certain clinical rooms, such as nursing, pharmacy, chemotherapy, and recovery needed special clinical benches and sinks. I participated in this process by communicating with Lenitudes' architect, by transmitting the clinical director' requirements and ideas, and contacting three suppliers: *Industrial Laborum, Iberdata* and *Bacelar*. The benches needed to be in inox or in corian, an antimicrobial material, with soft texture. The cabinets and respective trays were planned to be the same in all rooms, so that it can be easily adapt from ones to another. I also participated on the selection and size's definition of hospital curtains.

#### 3.2.2.2 Hospital Information Software (HIS)

I participated in several meetings regarding the Hospital Information Software. A company was responsible for the global software, another company with a model already predefined was responsible to provide software for radiotherapy and chemotherapy. The company that develops the global software is also responsible for the connection between all software to one, in order to ensure that information is centred in only one software.

Therefore, the global software should include the Electronic Clinical Process, with billing modalities, among others capabilities. It was very important to define the simultaneous users, the different access and permissions, which were critical factors to the budget proposal. The maintenance and technical assistance were also relevant factors to consider. The integration of the software with medical devices was also very discussed and assessed as crucial

requirement, especially for endoscopy equipment, vital signs monitors and other cardiac equipment. These connections were based on DICOM format of images and HL7 protocol of parameters, to ensure interoperability.

The outputs of this software that are provided to patients or to other physicians was also something that needed to be determine, if printed, if delivery through a pen-drive or by giving access to a portal on internet.

#### 3.2.2.3 Important Services

I was required to participate on meetings of budget requests related to waste management, laundry, hygiene and cleaning service. The process was very similar to medical devices meetings. After receiving their proposals, I developed Excel documents with comparison of price and service of each company. Although I did not participated in vigilance and security service meetings, I was requested to compare the price of different companies for this service as well.

### 3.2.3 Identification of needs and changes in the clinics structure (Site Visit)

During the several visits made to Lenitudes MC&R while it was under construction, several appointments were made in order to ensure that dimensions were in compliance with legislation and standards and to ensure future clinical good functioning. I collaborated in this process by giving administrative support to Clinical Director and Chief Nurse.

I checked the "Recommendations and Technical Specifications for Hospital Units" developed by ACSS and Portuguese Governmental Order nº 33/2014" of 12th February, in order to verify some clinical rooms, for example if consultation rooms had sufficient electric sources or in what rooms it is required to have a sink.

### 3.2.4 Research & Development

Although Research and Development (R&D) was not my core activity and in a phase where the clinical structure was in construction and development, I still had the opportunity to perform some R&D related activities.

#### 3.2.4.1 Medical Writing

I have collaborated as medical writer with Prof. Francisco Pimentel on Scientific Revision of the following publications:

- Laar;, E.S.V., J.M. Desai;, and A. Jatoi, *Professional Educational Needs for Chemotherapy-Induced Nausea and Vomiting*
- *(CINV): Multinational Survey Results From 2388 Healthcare Providers.* Supportive Care in Cancer, 2014.
- Pimentel, F.L., *Chapter 11 Lifestyle Changes*, in *Rehabilitation issues during cancer treatment and follow-up*, H.v. Halteren, Editor 2014, ESMO Handbook Series: ESMO Handbook Series. p. 115 - 124.

I have collaborated on the elaboration of the keywords list of two chapters:

- Pimentel;, F.L., A. Joaquim;, and S. Custódio, *Capítulo 29: Patologia oncológica e envelhecimento.* Geriatria Fundamental, 2014.
- Pimentel;, F.L., A. Joaquim;, and S. Custódio, *Capítulo 37: Cuidados Paliativos em idosos.* Geriatria Fundamental, 2014.

#### 3.2.4.2 Collaboration on R&D meetings

Lenitudes MC&R gives great importance to Research. Therefore it became important to assess which physicians and professors would be interesting in collaborating and developing R&D projects in Lenitudes.

The first meeting in Lenitudes MC&R regarding Research and Development occurred in 10th January 2015. Professors and Investigators from UA and the future Lenitudes' collaborators, in total twenty six participants, were present in this first meeting. I have collaborated on the meeting organization, being present on the meeting table and, together with Prof. Joana Silva from UA, on the development of the meeting minute. I have elaborated a survey as indicated before on quality section. After the meeting, I developed an Excel document with a list of all participants, with name, function, entity, contact and identification of Research interests, according to participant's answers to the survey. This document were then shared among participants.

The second meeting towards R&D that I have participated was related to a cardiac functioning project that occurred in 19th of March. It was mostly to plan the following steps, the definition of team members and transmission of the need to improve and adapt the project to increase probabilities of financial support within Horizon 2020 Programme. I analysed the draft of the

project and suggested some changes related with the structure of the document, addition of information and details, grammatical substitutions and some questions about particular aspects of the project, having as basis a form available on "EQUATOR Network" and on the knowledge developed during previous experiences and academic acquired during bachelor's and first year of master's degree [72].

#### 3.2.4.3 Analysis and Understanding of Horizon 2020 Programme

Lenitudes is interested on the submission to a Research Financial Support Programme. In Portugal, more specifically, on North region there is the "Norte 2020" Programme. However, their online site does not provide any specific information about the steps required to efficiently submit an application. Then, I searched on European Websites for Horizon 2020 and I found four important documents:

- Commission, E., *EC Horizon 2020 Research and Innovation Actions (RIA) Part A and Part B*, 2014.
- Commission, E., *EC Horizon 2020 AGA Annotated Model Grant Agreement*, 2014.
- Commission, E., *EC Horizon 2020 ERC Rules for Submission and Evaluation*, 2014.
- Commission, E., *EC Participant Portal H2020 Online Manual*: http://ec.europa.eu/research/participants/docs/h2020-funding-guide/index_en.htm.

After reading and understanding of the Horizon 2020 requirements and steps, I developed a General Plan for Application's Submission to Horizon 2020 Programme, which includes the big steps required to submit the project:

1. Read all applicable documentation;
2. Fill the Basic information about the proposal, study duration, keywords and abstract;
3. Definition of the Work Plan: Identification of work packages, deliverables and timelines;
4. Assurance of compliance with Ethical Principles;
5. Guarantee of Research Project's continuity;
6. Identification of all partners;
7. Protection issues: concerning personal data and environmental;
8. Data Management: identification of data that will be collected; analysis methods that will be used, among others;

9. Project Management Structure: description of the milestones and timelines; description of structure and decision-making
10. Description of the team members;
11. Estimation of resources;
12. Development of a Communication Plan for projects results;

This plan aims to help to adapt the research projects that Lenitudes will have and to facilitate the process of tasks and activities planning [73-76].

# 4 Training Sessions

During traineeship period, I participated on the following training sessions which have been of extremely importance to understand better quality related issues.

The next table lists the training courses that I attended.

Table 8 - List of Training Courses that I have attended

| Date | Tittle | Summary | Entity | Place |
|---|---|---|---|---|
| 3rd October 2014 | "IV Fórum ERS - Acreditação e Certificação em Saúde" | Presentation and discussion of 3 accreditation models (JCI, CHKS and ACSA) and certification by ISO | ERS – Entidade Reguladora da Saúde | Fundação Dr. António Cupertino de Miranda, Porto |
| 27-29th October 2014 | "Auditorias internas a sistemas de gestão da qualidade de dispositivos médicos ISO 13485" | Training Session about how to conduct an internal audit to QMS of medical devices according to ISSO 13485 | SGS - Société Générale de Surveillance S.A | Pólo De Serviços da Maia Rua Padre António, 232 Fracção 4.4 4470-136 Maia |
| 11-12th November 2014 | "Implementação de Sistemas de Gestão da Qualidade ISO 9001:2008" | Training session about how to develop and implement a quality management system according to ISO 9001:2008 | SGS - Société Générale de Surveillance S.A | Pólo De Serviços da Maia Rua Padre António, 232 Fracção 4.4 4470-136 Maia |
| 26th November 2014 | "Gestão de Afinidades em instituições de saúde" | Training session performed by Prof. Dr. Manuel Cardoso Oliveirato explain the importance of dealing with affinities in healthcare | Universidade Fernando Pessoa | Hospital-Escola da Universidade Fernando Pessoa Av.ª Fernando Pessoa, 150 4420-096 Gondomar |
| 20th February 2015 | "Avaliação Económica de tratamentos de cancro da próstata" | Conference about economic evaluation of prostate cancer treatment by a foreign investigator | CEISUC - Centro de Estudos e Investigação em Saúde da Universidade de Coimbra | Centro de Estudos e Investigação em Saúde da Universidade de Coimbra Av. Dias da Silva, 165 - 3004-512 Coimbra - Portugal |
| 21st March 2015 | "Cuidados Paliativos" | Presentation about palliative care presented by Prof. Francisco Pimentel in Master's degree in Geriatric | FMUC – Faculdade de Medicina da Universidade de Coimbra | Azinhaga de Santa Comba, Celas 3000-548 Coimbra |

# 5 Discussion

During first year of my Master's degree, I developed knowledge on clinical research and development, regulatory pharmaceutical legislation, medical devices regulation, research and development, pharmaceutical and health economics, Medical Drugs' pharmacovigilance, systematic review and meta-analysis. I attended to a subject called "Quality Management" on last year of my bachelor's degree that was common to students from health and engineering departments. Therefore, this subject was very general, not focusing on topics related to health, pharmaceutical or medical devices. At the end of first year of Master's degree, I felt a lack on quality management knowledge.

When I got the proposal to do my traineeship on Lenitudes MC&R, It was explained to me that this was a new health unit that was being built from scratch. It was indicated that top priorities of my tasks were medical devices budgets requests, management and organisation of information, support to clinical director and chief nurse work, and the core, quality management activities. I got very enthusiastic right from the beginning: I was having a very rare opportunity to follow and support the creation of a new health unit. At the beginning, for 7 months, the team was very small, being only the clinical director, chief nurse, AC (3 members), some Lenitudes holding-members and me (in total: 9 people). Therefore I had followed the majority of decisions related to Lenitudes MC&R. I followed the budget requests, medical devices' decision, unit's building/ civil construction, benches and cabinets decision, visits to clinical unit, commercial name selection (before it was called *Maio Clinic* and now Lenitudes MC&R), curriculum vitae submissions, clinics inauguration, information software decision, outsourcing services decisions, among others. Together with the enthusiasm it came the fear of the unknown and the start of something new. The closest members were, undoubtedly, the clinical director and chief nurse that advised me, supported my activities and made easier what seemed to be a difficult but a unique challenge.

As referred before, the core of my activities was quality related such as the creation of the accreditation plan. I already had knowledge on accreditation and certification designations and on ISO standards for certification, but health specific accreditation models and organisations were completely new for me. The Clinical Director advised me to search for JCI and for national accreditation model to start understanding this topic. The Chief Nurse, experienced in auditing also provided documentation on JCI and ISO standards and helped clarifying some issues. In order to have a better understanding, I have participated in three training courses, one provided by ERS and

the other two by SGS. In addition, I visited the quality department of *Hospital São Sebastião* to increase my knowledge towards clinical quality management systems.

I also contacted, via email, JCI, CHKS and OECI, to obtain more information on these specific models, putting into practice and improving my English and communication skills.

The quality management activities were, truly, a challenge. First, I tried to understand the accreditation models alone, clarifying some doubts with the experts, then to understand how a quality management system works and the requirements needed for an efficient QMS. I disagreed with the need to develop an accreditation plan on this initial phase, proposing that a quality management plan was more important and needed. I set the priorities of procedure development such as the documentation control that needs to be created first because it is essential to continue the QMS development, then the training procedure and equipment maintenance. I also developed a lot of standard records. The difficulties I felt were more related to approval and implementation. After the process of understanding and developing the documents, the conditions to proceed with approval and implementation of quality procedures were not gathered. Lenitudes MC&R was, still, in phase of selection of human resources, of medical devices and outsourcing services. The licences required to start operating were also not gathered yet. Nevertheless, each document that I have made towards quality, was shared with Clinical Director and Chief Nurse, and waited for new advances to be presented to administration council.

The medical devices management activities were also a great challenge. First, I have learnt how to communicate with suppliers, through email, phone and, more important, personally. I have participated in several meetings, I have understood the clinical characteristics for each device required by the physicians, I have learnt how to assess budget proposals, to give importance to clinical characteristics that are evaluated by the physicians and the technical assistance, discounts and time of assurance. With these activities I have learnt to be more communicative and specially, more organised. I received many budget proposals, and I was the one with the responsibility of recording and saving all these documents, including catalogues. I also developed many excel maps with list of equipment, suppliers and prices that also needed to be carefully organised. In these activities, another skill that I consider very relevant is the ability to pay attention to little details, so that none information is missed that could compromise the money spent and clinics functioning.

In the phase of development where Lenitudes MC&R was, there was quite complicated to ensure a correct time management, since there were times where decisions were being made, with tasks with extreme restrict schedules that needed to be performed as quickly as possible.

Since one characteristic of my personality is being perfectionist, at the beginning I had to deal with the fear of failure. This has happened more on medical devices management and requests to buy material to administration council, and on the activity of sending important documents to physicians. This “fear” had been diminishing as I was doing the tasks correctly.

During my traineeship, the activities related to medical devices management were transferred to another person that will be the responsible for this task. I have maintained quality management activities and added the clinical research and development tasks.

During the traineeship, I also gained more autonomy, regarding contact with suppliers and development of quality documents.

In summary, I think that I have achieved all objectives previous defined concerning master’s degree and my host organization aims. I contributed to the successful equipping and functioning of Lenitudes MC&R. I have a deep understanding of quality management systems and knowledge on some accreditation and certification models. I also know what an outpatient clinic with Lenitudes MC&R characteristics needs to have, regarding medical equipment. Furthermore, I know the medical devices market and the main Portuguese suppliers and producers.

Personally, I have developed the following soft skills: organisation and management, ability to work as a team, time management, ability to work under pressure, attention to details, responsibility sense and autonomy, communication skills, better understanding of my strengths and difficulties, adaptation to clinical environment and work schedules.

I can emphasise that I fulfilled all the objectives predefined, having felt more difficulties in management activities regarding quality and medical devices’ budgets.

# 6 Conclusion

The healthcare marketplace presents a high demand, having the search for Portuguese private healthcare services been increasing. Cancer and cancer survivors are also increasing, presenting clinical particularities and extra requirements [2, 3, 16, 17].

Lenitudes MC&R is a new health unit that aims to play a greater role towards oncological care, research and development projects. It has the ultimate technology concerning radiotherapy and nuclear medicine, electroporation and surgery procedures. It will develop several clinical research projects, participate on clinical trials, and the data generated will be continuously collected and analysed to give more reliable and valuable data, for a more secure and personalised medicine.

Quality is considered crucial to clinic's sustainability and growth. It is important for collaborators, suppliers, customers and to all stakeholders involved. It is one marketing strategy to attract foreign patients. For Lenitudes SGPS Company, the accreditation models evaluated in terms of suitability were CHKS's, JCI's, ACSA's and OECI's, whereas in terms of certification of quality management system, the ISO 9001:2008 standard was considered.

I feel glad for having had the opportunity to do my traineeship in Lenitudes MC&R. I achieved all the objectives predefined, and developed strong soft skills. Now I feel adapted to clinical environment. I had the chance to put into practice some knowledge acquired during academic training related with quality management, medical devices legislation, research and development. It made me grow both professionally and personally, making me more organized, communicative, autonomous and responsible.

It was, undoubtedly, a unique challenge that prepared me to have a complete view of the needs and requirements for a clinical unit to be equipped, to be in compliance with the applicable legislation and to start operating and functioning.

Therefore, I can conclude by emphasizing the fact that now I feel that I have the abilities and skills needed to face the labour market.

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# 8 Annexes

***Annex 1**: Quality Management Activities Planning*

*Table 9 - Quality Management Activities Plan*

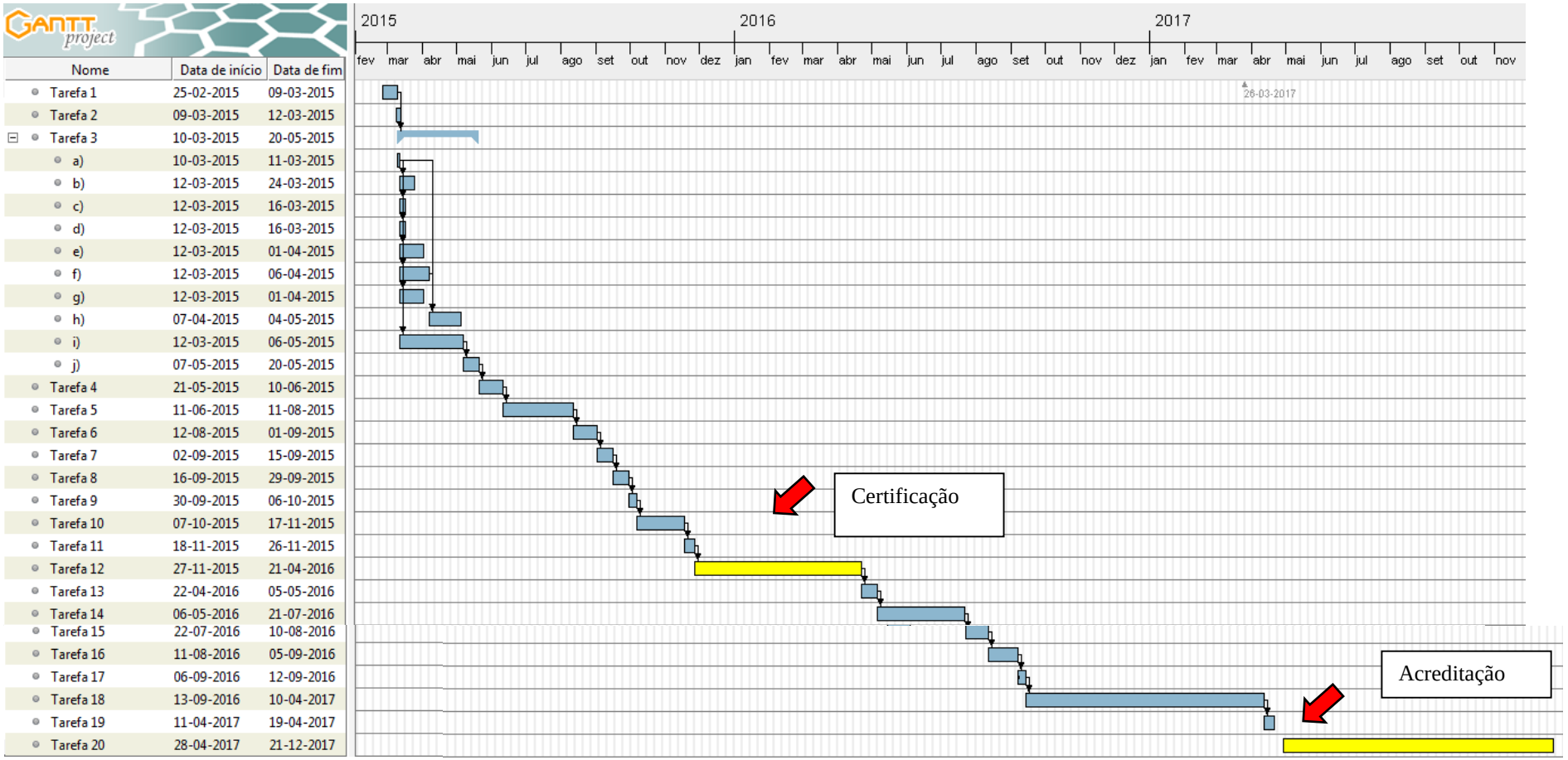
| Tarefa | Descrição | Duração | Período de Tempo após Aprovação do Plano | Observações |
|---|---|---|---|---|
| 1 | Reunião para Discussão do Tema "Qualidade" e Apresentação deste Plano:<br>o Identificação de possíveis alterações ao Plano<br>o Aprovação do Plano<br>o Identificação da Equipa da Qualidade (pelo menos 6 elementos)<br>▪ Coordenador<br>▪ Gestor da Qualidade<br>▪ Elementos de ligação (para colaborarem em algumas tarefas relacionadas com a qualidade, nomeadamente, reuniões, procedimentos de revisão e auditorias internas) constituídos por 1 colaborador de cada unidade<br>▪ Grupo de Trabalho Local: Equipa com elementos de todas as áreas | 2 Semanas | Semana 0-2 | Esta reunião deve ser efetuada até um mês antes do início das consultas |

| | | | | |
|---|---|---|---|---|
| | profissionais de cada uma das unidades funcionais | | | |
| 2 | Adquirir a norma ISO 9001:2008 | 1 Semana | Semana 3 | Custo ≈ 40,00€ |
| 3 | Iniciar a criação do Sistema de Gestão da qualidade de acordo com a Norma ISO 9001:2008 | | | |
| | a) Desenvolver o procedimento de controlo da documentação e toda a documentação associada; Aprovação e Implementação | 3 Dias | Semana 3 | O procedimento já foi elaborado; Falta aprovação e implementação<br>Após Execução da Tarefa 1;<br>Data Limite: 3 semanas antes do início da atividade clínica |
| | b) Desenvolver o Manual da Qualidade, identificar a política e os objetivos da empresa para a qualidade<br>Aprovação e Implementação | 2 Semanas | Semana 3 - 4 | Data Limite: 3 semanas antes do início da atividade clínica |
| | c) Desenvolver o procedimento de Ação de Formação e toda a documentação associada; Aprovação e Implementação | 3 Dias | Semana 3 | Após Execução da Tarefa 1 e 3a)<br>O procedimento já foi elaborado; Falta aprovação e implementação<br>Data Limite: 3 semanas antes do início da atividade clínica |
| | d) Desenvolver o procedimento de Receção e Manutenção de Equipamentos e todos os registos associados | 3 Dias | Semana 3 | Após Execução da Tarefa 1 e 3a)<br>O procedimento já foi elaborado; Falta aprovação e implementação<br>Data Limite: 3 semanas antes do início da atividade clínica |

| | | | | |
|---|---|---|---|---|
| | e) Desenvolver procedimentos de Emergência e Transferência de doentes; Aprovação e Implementação | 1 Semana | Semana 3 | Após Execução da Tarefa 1 e 3a)<br>Data Limite: 2 semanas antes do início da atividade clínica |
| | f) Desenvolver procedimentos específicos e de apoio às consultas e tratamento de quimioterapia; Aprovação e Implementação | 4 Semanas | Semana 3 - 7 | Após Execução da Tarefa 1 e 3a)<br>Data Limite: Imediatamente antes do início da atividade clínica |
| | g) Desenvolver o Plano de Gestão de Risco | 3 Semanas | Semana 3 - 6 | Após Execução da Tarefa 1 e 3a)<br>Data Limite: Imediatamente antes do início da atividade clínica |
| | h) Desenvolver procedimentos específicos e de apoio à CIR; Aprovação e Implementação; Atualizar Plano de Gestão de Risco | 4 Semanas | Semana 7 - 11 | Após Execução da Tarefa 1 e 3a)<br>Data Limite: Imediatamente antes do início da atividade cirúrgica |
| | i) Desenvolver procedimentos específicos e de apoio à RAD e MDN; Aprovação e Implementação; Atualizar Plano de Gestão de Risco | 8 Semanas | Semana 3-11 | Após Execução da Tarefa 1 e 3a)<br>Data Limite: Imediatamente antes do início o funcionamento do serviço de radioterapia e medicina nuclear |
| | j) Desenvolvimento da restante documentação de suporte ao SGQ e atualização da documentação necessária | 2 Semanas | Semana 11-13 | Após execução das Tarefas anteriores |
| 4 | Identificar indicadores de qualidade e métodos de medição | 3 Semanas | Semana 14 – 16 | Após execução das Tarefas anteriores |
| 5 | Análise dos Resultados da Qualidade | 8 Semanas | Semana 16 – 24 | Após execução das Tarefas anteriores |
| 6 | Apresentação dos Resultados e identificação de oportunidades de Melhoria | 2 Semanas | Semana 24 – 26 | Após execução da Tarefa anterior |

| | | | | |
|---|---|---|---|---|
| 7 | Identificar necessidade de certificação e seleção da empresa certificadora | 2 Semanas | Semana 26-28 | Após execução da Tarefa anterior |
| 8 | Realização e Apresentação do Plano de certificação | 2 Semanas | Semana 28-30 | Após execução da Tarefa anterior |
| 9 | Adquirir a nova versão 2015 da norma | 1 Semana | Semana 30 – 31 | Efetuar nova consulta de Preço |
| 10 | Verificação do cumprimento de todos os requisitos e especificações | 6 Semanas | Semana 31 – 37 | Após Aquisição da Norma e após realização da Tarefa 8 e 9 |
| 11 | Efetuar submissão do pedido de certificação à empresa selecionada | 2 Semanas | Semana 37 – 39 | Após Execução da Tarefa anterior |
| 12 | Efetuar todos os procedimentos e tarefas necessários para a obtenção da certificação do SGQ;<br>Obtenção de certificação do SGQ | 16 Semanas | Semana 39-55 | Após realização da Tarefa anterior |
| 13 | Após certificação do SGQ, atualizar política, objetivos e manuais da Qualidade | 2 Semanas | Semana 55-57 | Tarefa a ser realizada após obtenção da certificação |
| 14 | Melhoria de procedimentos e análise de resultados da qualidade | 10 Semanas | Semana 57 – 67 | |
| 15 | Avaliação da necessidade de acreditação e seleção da empresa acreditadora | 2 Semanas | Semana 67-69 | - |

| | | | | |
|---|---|---|---|---|
| 16 | Elaboração e Apresentação do Plano de Acreditação | 3 Semanas | Semana 69 – 72 | - |
| 17 | Mediante autorização, proceder à aquisição do manual | 1 Semana | Semana 72-73 | Custo ≈ 127,44€ |
| 18 | Verificação do cumprimento dos requisitos e possíveis alterações | 30 Semanas | Semana 73 - 103 | Após aquisição dos Manuais |
| 19 | Efetuar submissão do pedido de acreditação à empresa selecionada | 2 Semanas | Semana 103 – 104 | Após execução da Tarefa anterior |
| 20 | Efetuar todos os procedimentos e tarefas necessários para a obtenção da acreditação;<br>Obtenção de acreditação | 32 Semanas | Semana 104 – 136 | Após Realização da Tarefa anterior<br>- |




| Nome | Data de início | Data de fim |
|---|---|---|
| Tarefa 1 | 25-02-2015 | 09-03-2015 |
| Tarefa 2 | 09-03-2015 | 12-03-2015 |
| Tarefa 3 | 10-03-2015 | 20-05-2015 |
| a) | 10-03-2015 | 11-03-2015 |
| b) | 12-03-2015 | 24-03-2015 |
| c) | 12-03-2015 | 16-03-2015 |
| d) | 12-03-2015 | 16-03-2015 |
| e) | 12-03-2015 | 01-04-2015 |
| f) | 12-03-2015 | 06-04-2015 |
| g) | 12-03-2015 | 01-04-2015 |
| h) | 07-04-2015 | 04-05-2015 |
| i) | 12-03-2015 | 06-05-2015 |
| j) | 07-05-2015 | 20-05-2015 |
| Tarefa 4 | 21-05-2015 | 10-06-2015 |
| Tarefa 5 | 11-06-2015 | 11-08-2015 |
| Tarefa 6 | 12-08-2015 | 01-09-2015 |
| Tarefa 7 | 02-09-2015 | 15-09-2015 |
| Tarefa 8 | 16-09-2015 | 29-09-2015 |
| Tarefa 9 | 30-09-2015 | 06-10-2015 |
| Tarefa 10 | 07-10-2015 | 17-11-2015 |
| Tarefa 11 | 18-11-2015 | 26-11-2015 |
| Tarefa 12 | 27-11-2015 | 21-04-2016 |
| Tarefa 13 | 22-04-2016 | 05-05-2016 |
| Tarefa 14 | 06-05-2016 | 21-07-2016 |
| Tarefa 15 | 22-07-2016 | 10-08-2016 |
| Tarefa 16 | 11-08-2016 | 05-09-2016 |
| Tarefa 17 | 06-09-2016 | 12-09-2016 |
| Tarefa 18 | 13-09-2016 | 10-04-2017 |
| Tarefa 19 | 11-04-2017 | 19-04-2017 |
| Tarefa 20 | 28-04-2017 | 21-12-2017 |

*Figure 13 - Time chart of Quality Management Approach*

***Annex 2:*** *SOP for Documentation Control (first page and some tables presented in this SOP)*

| [Logo + brand da unidade] | **Nome do documento:** Controlo da Documentação | | Página 1 de 13 |
|---|---|---|---|
| | **Tipo de documento:** Procedimento | **Nº/Versão:** | **Data da 1ª versão:** |
| **Elaboração em:** | **Revisão em:** | **Aprovação em:** | **Revogação em:** |
| **Por:** [Nome do colaborador (função)] | **Por:** [Nome do colaborador (função)] | **Por:** [Nome do colaborador (função)] | **Por:** [Nome do colaborador (função)] |

## 1. Âmbito:

Este documento encontra-se inserido no âmbito do Sistema de Gestão da Qualidade das unidades de saúde pertencentes ao grupo Lenitudes SGPS.

## 2. Objetivos:

Este procedimento uniformiza e estabelece as regras e métodos necessários para a identificação, elaboração, revisão, atualização, aprovação, distribuição, arquivo e controlo de documentos, no âmbito do Sistema de Gestão de Qualidade.

Desta forma, pretende-se:

- Assegurar que os documentos em vigor e as respetivas versões, alterações e revisões encontram-se devidamente identificados;
- Garantir que a versão atual, revista e aprovada de todos os documentos é facilmente identificável e localizada, permitindo a sua correta utilização quando e onde é necessária;
- Os documentos de origem externa sejam identificados como tal e convenientemente distribuídos e controlados;
- Os documentos obsoletos sejam devidamente identificados, prevenindo a sua utilização incorreta.

## 3. Campo de Aplicação/ Destinatários:

Este procedimento aplica-se a todas as áreas da Lenitudes SGPS integradas no SGQ, pelo que deve ser aplicado a todos os documentos inseridos neste sistema, e respeitado por todos os colaboradores. Sempre que algo não for aplicável, deve-se colocar a indicação "Não Aplicável".

*Figure 14 - First Page of SOP for Documentation Control*

*Table 10 - Codification of entities belonging to Lenitudes' Group*

| Organização: | Codificação: |
|---|---|
| Lenitudes SGPS | 01 |
| Lenicare, Évora | 10 |
| Lenitudes Medical Center & Research | 11 |
| Hospital Cirúrgico Setúbal | 12 |
| Hospital de Portimão | 13 |

*Table 11 - Codification of major areas and services of each Lenitudes' unit*

| Área | Código | Subgrupo | Código |
|---|---|---|---|
| **Gestão** | **1** | Conselho de Administração | 1 |
| | | Comissões/Órgãos Técnicos | 2 |
| | | Administração/ Secretariado | 3 |
| | | Recursos Humanos | 4 |
| | | Qualidade | 5 |
| | | Financeira | 6 |
| | | Outros | 9 |
| **Clínica** | **2** | Oncologia | 1 |
| | | Radioterapia | 2 |
| | | Medicina Nuclear | 3 |
| | | Imagiologia | 4 |
| | | Cirurgia | 5 |
| | | Enfermagem | 6 |
| | | Técnicos Superiores | 7 |
| | | Documentos Gerais | 8 |
| | | Outros | 9 |
| **Serviço de Apoio** | **3** | Farmácia | 1 |
| | | Esterilização | 2 |

| | | | |
|---|---|---|---|
| | | Morgue | 3 |
| | | Aprovisionamento | 4 |
| | | SIES | 5 |
| | | Higiene e Limpeza | 6 |
| | | Laboratórios de patologia clínica, anatomia patológica e genética | 7 |
| | | Outros | 9 |
| **Outros** | **9** | A definir | 1 |

*Table 12 - Types of Documents available in Lenitudes' units*

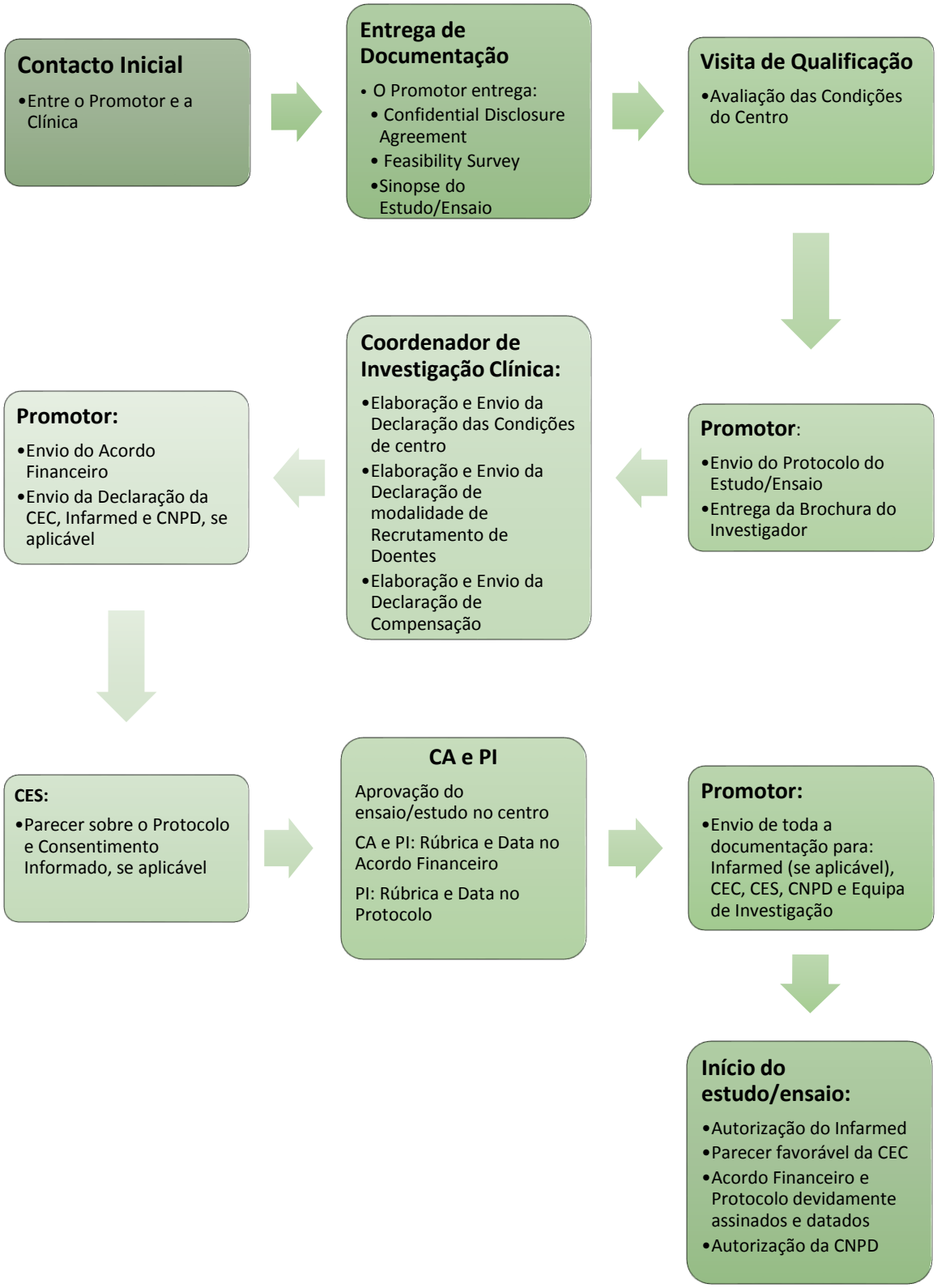
| Nível | Tipo de Documento | Código | Descrição |
|---|---|---|---|
| 1 | **Política** | 01 | Conjunto de regras e diretrizes definidas pelo conselho de administração tendo em conta a estratégia de mercado, visão e valores da empresa. |
| | **Regulamento** | 02 | Conjunto de regras, direitos e obrigações de carácter normativo de forma a regular a atividade e funcionamento da organização. |
| | **Norma** | 03 | Documento elaborado pelo Conselho de Administração de índole normativa. |
| | **Informação** | 04 | Documento elaborado pelo Conselho de Administração de cariz informativo. |
| 2 | **Manual** | 05 | Documento que inclui as informações sobre um determinado assunto ou equipamento, incluindo instruções e orientações de funcionamento e utilização. |
| 3 | **Acordo** | 06 | Conjunto de informações relativas à concordância e acordo de um ou mais aspetos, celebrado entre as partes interessadas. |
| | **Plano** | 07 | Conjunto de orientações e estratégias definidas de forma a cumprir os objetivos enunciados na Política e noutros documentos elaborados pelo CA. |
| | **Procedimento** | 08 | Documento que define e descreve as etapas e métodos necessários para a realização de uma determinada tarefa/atividade. |
| | **Protocolo** | 09 | Conjunto de orientações e regras que visam um entendimento entre os diversos intervenientes. |
| 4 | **Instruções de Trabalho** | 10 | Conjunto de esclarecimentos e orientações referentes ao modo de execução de uma tarefa/atividade. |
| | **Instruções de Segurança** | 11 | Conjunto de orientações de segurança que visam a prevenção, minimização, ou eliminação de riscos. |
| | **Ficha de Segurança** | 12 | Conjunto de informações relacionadas com um determinado produto ou substância no que diz respeito ao risco, utilização/manuseamento e condições de armazenamento. |
| | **Folheto de Informação** | 13 | Conjunto de informações de caracter diverso, destinado aos colaboradores, pacientes, familiares, convidados e visitas. |
| | **Documento externo** | 14 | Documento elaborado, revisto ou alterado por uma unidade externa ao SGQ. |
| 5 | **Impressos** | 15 | Documento com campos de registo. |

***Annex 3**: Technical Assistance Report*

<table>
<tr><th colspan="3">Intervenção</th></tr>
<tr><td colspan="2">Preventiva ☐</td><td>Curativa ☐</td></tr>
<tr><td>Interna ☐</td><td>Externa ☐</td><td>Data de deteção da Anomalia:</td></tr>
<tr><td colspan="2">Se a intervenção for realizada por uma empresa externa, o técnico apenas tem que preencher as linhas até à "identificação do documento" e a última, ficando responsável por garantir que a empresa externa entregue toda a documentação associada.</td><td>Colaborador que detetou a anamolia e contactou o SIES:<br>Nome:<br>NºMec.:</td></tr>
<tr><td colspan="2">Identificação do equipamento:<br>Nome:<br>Código:<br>Localização:</td><td>Identificação do equipamento:<br>Nome:<br>Código:<br>Localização:</td></tr>
<tr><td colspan="2">Avaliação do Equipamento<br>(de acordo com a ordem apresentada)</td><td>Avaliação do Equipamento<br>(de acordo com a ordem apresentada)</td></tr>
<tr><td colspan="2">O equipamento apresenta riscos para a <u>segurança das pessoas</u>?<br>Sim ☐ Não ☐<br>Se sim, efetuar imediatamente os procedimentos de segurança.</td><td>O equipamento apresenta riscos para a <u>segurança das pessoas</u>?<br>Sim ☐ Não ☐<br>Se não, efetuar imediatamente os procedimentos de segurança.</td></tr>
<tr><td colspan="2">As <u>infraestruturas e os espaços</u> estão salvaguardados:<br>Sim ☐ Não ☐<br>Se não, avaliar de que forma se pode minimizar os estragos.</td><td>As <u>infraestruturas e os espaços</u> estão salvaguardados:<br>Sim ☐ Não ☐<br>Se não, avaliar de que forma se pode minimizar os estragos.</td></tr>
<tr><td colspan="2"><u>Performance/Funcionalidade</u> do Equipamento:<br>De 0 a 5 classifique a performance do equipamento, tendo em conta, as suas características-base:<br>1 | 2 | 3 | 4 | 5<br>Detetou alguma anomalia?<br>Sim ☐ Não ☐</td><td><u>Performance/Funcionalidade</u> do Equipamento:<br>Identificação da falha:<br>Sugestão de correção e reparação:<br>Caso não tenha conseguido identificar a falha, por favor assinale: ☐</td></tr>
</table>

| | |
|---|---|
| Procedimentos de manutenção realizados: | Procedimentos realizados: |
| O Equipamento cumpre as normas e está a funcionar corretamente?<br>Sim ☐ Não ☐<br>Se não, iniciar intervenção curativa.<br><br>Data prevista da Próxima manutenção: | Equipamento reparado:<br>Sim ☐ Não ☐<br>Se não, contacte a empresa fornecedora.<br><br>Para equipamentos que não foram reparados, existe a possibilidade de substituição/compra do equipamento?<br>Sim ☐ Não ☐<br>Se sim, expor a situação ao Diretor clínico e posteriormente ao Conselho de Administração. |
| **Técnico responsável**<br>Nome:<br>Nº Mec.: ____/____/____<br>_____<br>(o técnico) | **Técnico responsável**<br>Nome:<br>Nº Mec.: ____/____/____<br>_____<br>(o técnico) |

***Annex 4:*** *Schematic Procedure to receive and accept a clinical trial or study*




**Nota:** Os documentos e a respetiva ordem aqui representados podem não corresponder exatamente à realidade para todos os ensaios/estudos, visto estes poderem ser promovidos por entidades diferentes.

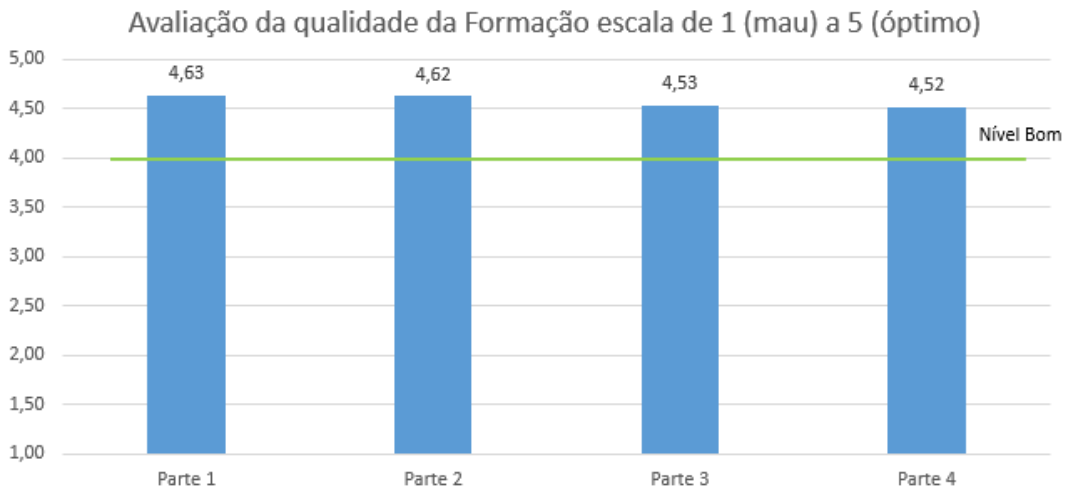
***Annex 5**: Results of a Quality analysis to a Training Session*

**Parte 3: Processo de Implementação do Serviço de Radioterapia** **Coordenador:**

| Componente de Avaliação | Nº respostas por Classificação | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | N/A | Total respostas | Média |
| O tema da Sessão é do seu interesse | 0 | 0 | 2 | 5 | 7 | 0 | 14 | 4,36 |
| Os espaços foram adequados | 0 | 0 | 1 | 2 | 11 | 0 | 14 | 4,71 |
| Equip. Audiovisuais apropriados | 0 | 0 | 1 | 2 | 11 | 0 | 14 | 4,71 |
| Horário adequado e cumprido | 0 | 1 | 0 | 4 | 9 | 0 | 14 | 4,50 |
| Sessão e conteúdos de acordo com as expectativas | 0 | 0 | 1 | 5 | 8 | 0 | 14 | 4,50 |
| Os conhecimentos adquiridos são úteis | 0 | 1 | 1 | 4 | 8 | 0 | 14 | 4,36 |
| O coordenador cumpriu os objectivos e sumário | 0 | 0 | 1 | 1 | 11 | 1 | 14 | 4,43 |
| O coordenador explicou de forma clara e concisa | 0 | 0 | 1 | 2 | 11 | 0 | 14 | 4,71 |
| O coordenador mostrou-se disponível para esclarecimento de dúvidas | 0 | 0 | 1 | 2 | 10 | 1 | 14 | 4,36 |
| | | | | | | | Total | 4,52 |

| | | |
|---|---|---|
| **Nº Falhas de respostas ao questionário:** | 1 | Apenas à parte 4 do questionário |
| **Classificação da Formação (Escala 1-5)** | 4,58 | **Muito Bom** |

| **Observações** |
|---|
| "Parabéns pela Excelência que já demonstram; Votos de Sucesso" |
| "Pessoalmente, agradeço toda a disponibilidade e simpatia" |
| "Agradeço a oportunidade concedida para a visita às instalações e conhecimento dos equipamentos. Espero que a motivação para a investigação se mantenha e que a Lenitudes se torne um Centro de Excelência" |
| "A oportunidade de visitar um centro deste calibre num momento anterior ao início da sua atividade clínica foi extraordinário" |
| "Reparei que foi tudo muito bem planeado ao pormenor. Parabéns pela Excelência" |
| "Esperava apenas uma visita guiada, pelo que as apresentações, num espaço mais formal, foi positivo" |



***Annex 7:*** *UA's newsletter showing the event of UA's students visit to Lenitudes MC&R*

Campus
Cultura
Desporto
Bolsas
Conferências
Concursos e Prémios
Distinções
Divulgação de Ciência
Emprego
Ensino e Formação
Investigação
Provas Académicas

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Rede de Investigação e Educação em Turismo para a Lusofonia em destaque no Click

Bolsa para Licenciado em Bioquímica

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**DEM** DLC it DQ **sasua** **Formação** **DECA** **DETI** **Fábrica** degei **Dbio** **CESAM** Biologia ação ciceco **UNAVE**

Campus

Na sequência da formalização do relacionamento institucional no passado dia 4 de fevereiro

# Visita de Estudo de alunos da Universidade de Aveiro ao Lenitudes Medical Center & Research

3.3.2015

No passado dia 26 de fevereiro, a Lenitudes Medical Center & Research recebeu os alunos do Mestrado "Tecnologias de Imagem Médica" da Universidade de Aveiro. Esta ação de formação teve como objetivos a apresentação do Equipamento de Medicina Nuclear, Imagem Molecular e de Radioterapia, e uma contextualização prática das atividades necessárias e as dificuldades sentidas nos processos de implementação destes mesmos equipamentos.

Esta visita contou com a presença do Diretor Clínico da Unidade, o Prof. Doutor Francisco Pimentel, do Engenheiro João Cunha Pires em representação da General Eletrics, do Engenheiro Ricardo Freitas em representação da Avanço e as Engenheiras Catarina Souto e Lia Silva, membros da equipa da Lenitudes.

Recorde-se que a formalização do relacionamento institucional entre a UA e a Lenitudes Medical Center & Research decorreu no passado dia 4 de Fevereiro por intermédio do Reitor da UA e da Direção do Lenitudes Medical Center & Research através da assinatura dum protocolo de colaboração. O evento que aqui se reporta inaugura no terreno uma série de iniciativas conjuntas no âmbito do ensino e da investigação na área das ciências e tecnologias da saúde que legitimam as mais elevadas expectativas de ambas as instituições.

A comitiva da UA constituída por alunos e docentes, seguiu com enorme interesse durante as cerca de 4 horas uma sessão marcada por apresentações "in loco" dos mais avançados sistemas de imagem médica de apoio ao diagnóstico e à terapêutica.

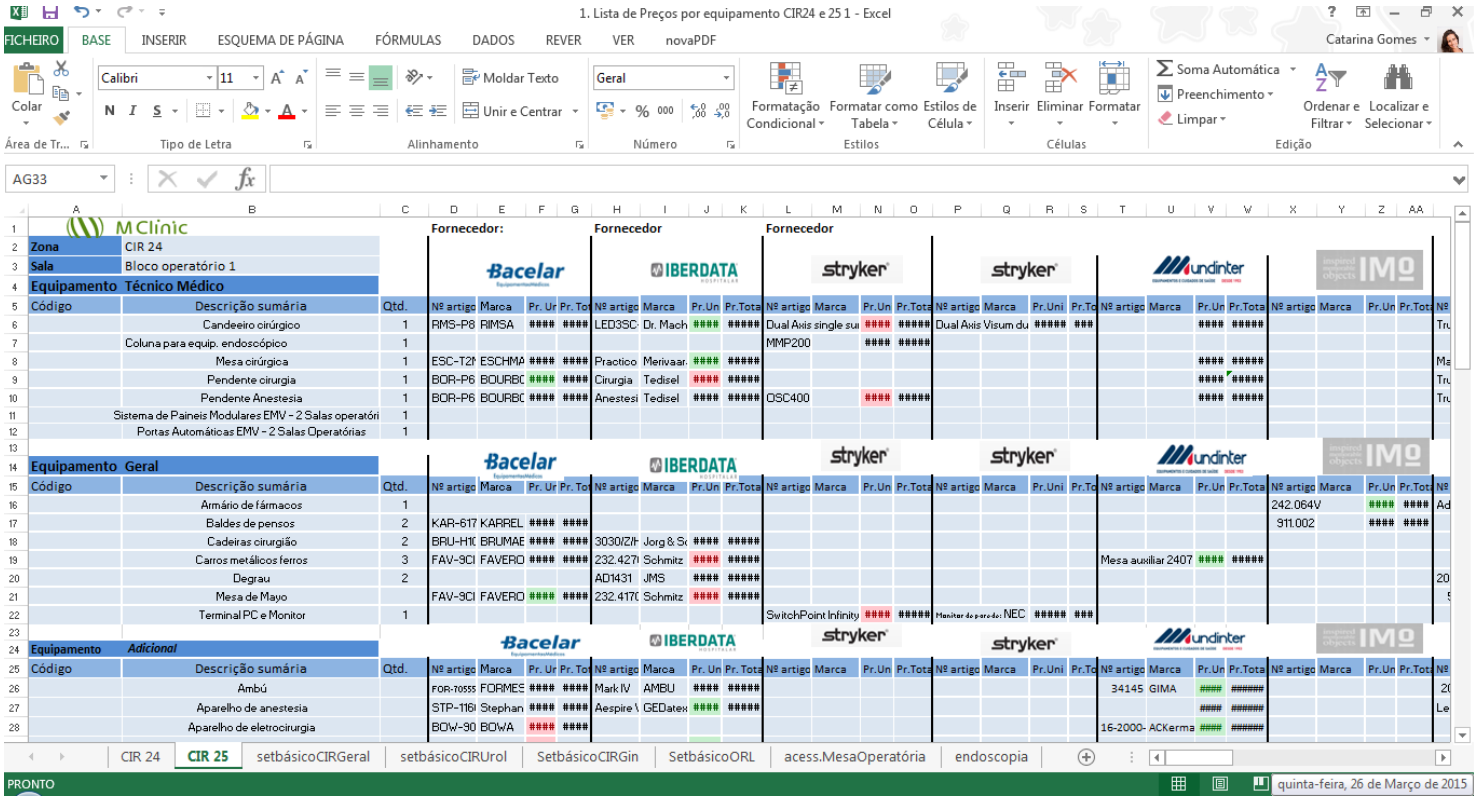
Os alunos consideraram esta visita como uma oportunidade única de formação no sentido em que é muito raro poderem assistir tão precocemente ao arranque funcional de infraestruturas imagiológicas.

Nas palavras de Cátia Campos, aluna do Mestrado em Tecnologias de Imagem Médica da UA: "A oportunidade de visitar um centro deste calibre num momento anterior ao início da sua atividade clínica foi extraodinário".

**veja também**

Parceria da UA com centro de investigação oncológica reforça a aposta da academia na Saúde

***Annex 7:*** *List of Medical equipment by room (in this case surgery room)*



***Annex 8:*** *List of Medical equipment by type of equipment (in this case vital signal monitors)*